UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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: 001-39593

Shattuck Labs, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**81-2575858**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

500 W. 5th Street, Suite 1200
Austin, TX 78701
(512) 900-4690

(Address of principal executive offices including zip code)
Former name, former address and former fiscal year, if changed since last report: N/A

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	STTK	The Nasdaq Global Select Market

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

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

Indicate by a 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, a 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 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, was approximately $22,826,702 based on the closing price on The Nasdaq Global Select Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded as such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 26, 2026 the registrant had 71,564,217 shares of common stock, $0.0001 par value per share, outstanding.

Documents Incorporated by Reference

The information required by Part III of this Annual Report, to the extent not set forth herein, is incorporated by reference to the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2026, which is expected to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates.

Auditor Firm ID: 185 Auditor Name: KPMG LLP Auditor Location: Austin, TX, USA

SHATTUCK LABS, INC.
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CAUTIONARY NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to products and markets, and business trends and other information referred to under the sections entitled "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business" are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan," "develop", or the negative of these terms, and similar expressions intended to identify forward-looking statements. Forward-looking statements are not historical facts, and reflect our current views with respect to future events, outcomes or results. Given the significant risks and uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties and other factors that could cause our actual results or outcomes, or the timing of our results or outcomes, to differ materially from the forward-looking statements expressed or implied in this Annual Report on Form 10-K. Such risks, uncertainties and other factors include, among others, the following:

- the timing of the initiation, progress, and expected results of our nonclinical studies, our clinical trials, and our research and development programs;
- our ability to enroll patients in our clinical trials;
- the costs related to our nonclinical studies, our clinical trials, our research and development programs, and the impact of inflationary pressures on such costs;
- our ability to retain the continued service of our key executives and to identify, hire, and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, nonclinical studies and clinical trials;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our product candidates, if approved;
- our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- the pricing, coverage, and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology;
- our potential need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated;
- our ability to enter into strategic arrangements and/or collaborations and to realize the potential benefits of such arrangements;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our estimates regarding the market opportunity for our product candidates, if approved;
- our estimates regarding expenses, capital requirements, and needs for additional financing and our ability to obtain additional capital;
- our financial performance;
- developments relating to our competitors and our industry, including competing product candidates and therapies; and
- economic downturns, inflation, fluctuating interest rates, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, natural disasters, public health crises, such as pandemics, political crises, government shutdowns, geopolitical events, or other macroeconomic conditions.

There may be other risks, uncertainties, and other factors that may cause our actual results or outcomes, or the timing of our results or outcomes, to differ materially from the forward-looking statements expressed or implied in this Annual Report on Form 10-K, including factors disclosed under the sections entitled in "Risk Factors," and "Management's Discussion and

Analysis of Financial Condition and Results of Operations". You should evaluate all forward-looking statements made in this Annual Report on Form 10-K in the context of these risks and uncertainties and other factors.

We caution you that the risks, uncertainties, and other factors referred to above and elsewhere in this Annual Report on Form 10-K may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. In addition, we cannot assure you that we will realize the results, outcomes, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way we expect.

Any forward-looking statements contained in this Annual Report on Form 10-K speak only as of the date hereof and not of any future date, and we expressly disclaim any intent to update any forward-looking statements, whether as a result of new information, future developments, future events, changes in assumptions or otherwise.

Part I.

In this Annual Report on Form 10-K, unless the context requires otherwise, references to "we," "us," "our," "Shattuck Labs," "Shattuck," or the "Company" refer to Shattuck Labs, Inc. Additionally, references to our "Board" refer to the board of directors of Shattuck Labs, Inc.

Item 1. Business

Overview

We are a clinical-stage biotechnology company pioneering the development of potentially first-in-class monoclonal and bispecific Death Receptor 3 ("DR3") blocking antibodies for the treatment of patients with inflammatory and immune-mediated diseases. Our expertise in protein engineering and the development of novel tumor necrosis factor ("TNF") receptor therapeutics come together in our lead program, SL-325, a potentially first-in-class DR3 blocking antibody designed to achieve a more complete blockade of the clinically validated DR3/TL1A pathway than TL1A blocking antibodies.

SL-325 is a high-affinity DR3 blocking monoclonal antibody. DR3 is the sole known receptor for tumor necrosis factor like ligand 1A ("TL1A"). In our head-to-head preclinical studies, SL-325 blocked TL1A binding to DR3 better than sequence equivalents of leading TL1A blocking antibodies. We believe that the underlying biological differences in the expression of DR3 and TL1A, and the design characteristics of SL-325, may allow SL-325 to achieve best-in-class clinical remission rates in patients with IBD due to a more complete and durable blockade of the clinically validated DR3/TL1A pathway. Additionally, we expect that SL-325 has the potential to demonstrate a superior immunogenicity profile in comparison to TL1A blocking antibodies. By targeting DR3 instead of TL1A, we expect to avoid the formation of immune complexes, which we believe are the primary source of immunogenicity for all TL1A blocking antibodies, and lead to high rates of anti-drug antibody ("ADA") formation toward TL1A targeting antibodies. ADA to TL1A targeting antibodies has been shown to reduce efficacy in IBD patients. We are currently conducting a single ascending dose ("SAD") and multiple ascending dose ("MAD") Phase 1 clinical trial evaluating SL-325 in healthy volunteers. We expect this Phase 1 clinical trial to be completed in the second quarter of 2026. We expect to initiate a randomized, placebo-controlled Phase 2 clinical trial evaluating SL-325 in patients with Crohn's Disease ("CD") in the third quarter of 2026.

TL1A is the sole known signaling ligand for DR3, and TL1A does not signal through any other receptors. Thus, we believe that the clinical safety profile of TL1A blocking antibodies generated to date in clinical trials conducted by other parties derisks the clinical safety profile for DR3 blockade. The lack of toxicity of SL-325 in our recently completed non-human primate ("NHP") acute toxicology study also suggests a potentially favorable clinical safety profile. We engineered SL-325 to lack any Fc gamma receptor binding function, and SL-325 has not shown any evidence in our preclinical studies to date of antibody dependent cellular cytotoxicity or cellular phagocytosis, which further supports a potentially derisked safety profile. We have demonstrated that SL-325 binds an epitope on DR3 that does not trigger receptor-mediated endocytosis, and the binding of SL-325 to DR3 was shown to be highly durable in our preclinical assays and in our NHP studies. Because DR3 is expressed on circulating, peripheral blood lymphocytes, we are able to directly measure DR3 receptor occupancy ("RO"), and our nonclinical studies suggest that blockade is durable for at least two months as a result of the properties of SL-325 and the stable expression of DR3. In our preclinical studies, including our acute NHP toxicology study, the RO and pharmacokinetic ("PK") profile of SL-325 suggest extended dosing intervals, which are being further characterized in our ongoing Phase 1 clinical trial.

DR3 has a distinct expression pattern from TL1A, and, consequently, blocking the receptor may allow a more complete and durable blockade of the axis, which we believe will translate to improved efficacy in patients with IBD. DR3 and TL1A have distinct expression patterns within the gastrointestinal tract ("GI") of patients with IBD, including both ulcerative colitis ("UC") and Crohn's disease ("CD"). The cells within the GI tract that are capable of expressing TL1A include tissue resident antigen presenting cells and other non-hematopoietic cells. While TL1A is not usually expressed, when antigen presenting cells are exposed to inflammatory signals, a wave of TL1A mRNA expression begins, which peaks within 12 hours and ceases within 24 hours. In contrast, DR3 is stably expressed, primarily by lymphocytes both in the peripheral blood and in tissues. Direct comparison of TL1A and DR3 expression in the GI tracts of patients with IBD shows that TL1A is only upregulated in the actively inflamed areas of the GI tract. In contrast, DR3 is more abundant than TL1A and is upregulated in both actively inflamed parts of the GI tissue and in the adjacent non-inflamed tissue. The absence of TL1A in the non-inflamed areas of the bowel eliminates the mechanism through which TL1A blocking antibodies would be retained in non-inflamed areas of the GI tract. Because inflammation observed in UC and CD can wax and wane in different areas of the bowel over time, stable blockade of DR3 may reduce the spread of inflammation and may contribute to higher rates of clinical and endoscopic remission than what TL1A blocking antibodies have achieved to date.

A source of immunogenicity shared by all TL1A blocking antibodies is the formation of immune complexes between soluble TL1A in the blood and the anti-TL1A antibodies. Binding of soluble TL1A in the blood by anti-TL1A antibodies leads to a significant increase in the concentration of total TL1A in the blood. These immune complexes have contributed to ADA

formation in more than 64% of subjects treated with afimkibart, tulisokibart, or duvakitug in third-party clinical trials. A third-party Phase 2 trial testing the efficacy of afimkibart in CD patients demonstrated that ADA caused accelerated clearance of afimkibart, which reduced efficacy in an ADA titer dependent manner. Because DR3 is a membrane-restricted receptor, and SL-325 was engineered to bind an epitope on DR3 that is not found on DcR3, immune complex formation is not expected with SL-325. Data generated from our GLP acute NHP toxicology study, along with *in silico* assessment of immunogenicity risk, consistently suggest that SL-325 may have single digit ADA rates in humans. Thus, we expect that SL-325 has the potential to demonstrate a best-in-mechanism immunogenicity profile, and we expect that this superior immunogenicity profile alone will lead to improved efficacy as a monotherapy, at both the induction and maintenance time points.

Additionally, there is a high degree of sequence identity between certain third-party anti-TL1A antibodies, including tulisokibart, afimkibart, and duvakitug, and potential third-party combination agents, including vedolizumab, risankizumab, mirikizumab, and guselkumab. This overlap in sequence identity introduces a risk that ADAs generated against TL1A antibodies may cross-bind to these potential combination agents and could cause accelerated clearance of both the anti-TL1A antibody and other antibodies included in a coformulation, and that this may impact the efficacy of each agent. Because of this, we believe that SL-325 may allow for improved efficacy in combination with other agents, compared to TL1A targeting antibodies.

We are planning initial clinical development of SL-325 in patients with CD. The clinical success of several TL1A blocking antibodies to date suggests that SL-325 may have monotherapy disease modifying activity early in clinical development. As described above, we believe that targeting DR3 may be more efficacious than targeting TL1A in patients with IBD. We expect to complete enrollment in the ongoing Phase 1 clinical trial for SL-325 in healthy volunteers in the second quarter of 2026, and initiate our Phase 2 clinical trial in patients with CD in the third quarter of 2026.

We also plan to evaluate SL-325 in other inflammatory and immune-mediated diseases where the DR3/TL1A axis is implicated.

In addition to SL-325 and SL-425 (a half-life extended version of SL-325), we are developing bispecific antibodies which co-target DR3 and other clinically validated targets in immune mediated and inflammatory diseases. Inhibition of the TL1A/DR3 axis may be mechanistically distinct from the IL-23/IL-23R, IL-17/IL-17R, TSLP/TSLP-R or α4β7/MADCAM-1 axes (as examples). Thus, dual inhibition of the TL1A/DR3 axis with coformulated or bispecific antibodies may provide additive clinical benefit in a variety of immune mediated and inflammatory diseases. As seen with TL1A directed antibodies, two third-party TL1A-directed bispecific antibodies, AMG966 and RO7837195, have also demonstrated nearly 100% ADA formation following a single dose in Phase 1 clinical trials. The mechanism of ADA formation was reported to be secondary to large immune complex formation for AMG966, which we believe is also true for RO7837195. The emerging clinical data from TL1A-directed bispecific antibodies is similar to the prior failure of TNFα-directed bispecific antibodies, which we believe is because both TNFα and TL1A are soluble trimeric proteins found in the blood, and cause immunogenicity secondary to large immune complex formation. We expect that our DR3-directed bispecific antibodies to be less immunogenic than TL1A-directed bispecifics. DR3 may thus provide a differentiated target in a bispecific antibody format, providing advantages over TL1A-directed bispecific antibodies. Additionally, development of bispecific antibodies may enable more efficient clinical development than is expected for multi-antibody coformulations, and may avoid some of the challenges associated with potential immunogenicity in certain coformulations, as described above.

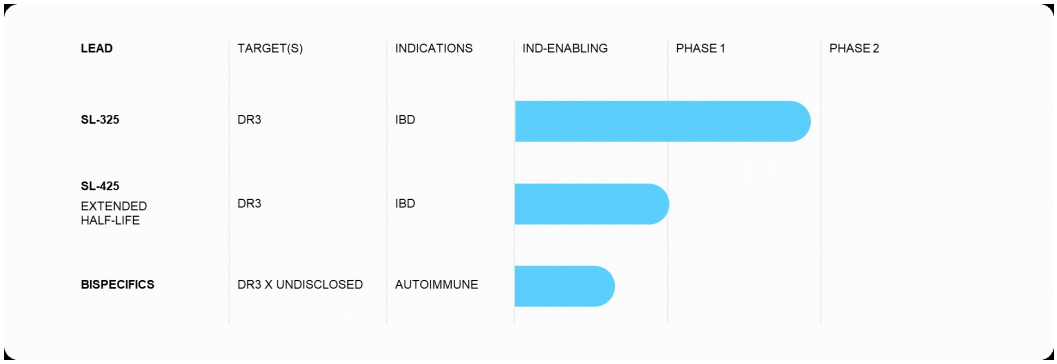
Our Pipeline

Our lead product candidate, SL-325, is a monoclonal antibody that is designed to bind to DR3 and inhibit its interaction with its ligand, TL1A. We have completed an IND-enabling, good laboratory practices ("GLP") toxicity study to evaluate the safety and tolerability of SL-325 in NHPs. We are currently conducting a SAD/MAD Phase 1 clinical trial in healthy volunteers to evaluate the safety, tolerability, pharmacokinetics, and immunogenicity of SL-325, and to establish the Phase 2 dose and dosing schedule. We expect to complete enrollment in the Phase 1 clinical trial in the second quarter of 2026, and to initiate a Phase 2 clinical trial in CD patients in the third quarter of 2026.

In addition to SL-325, we are developing SL-425, a half-life extended version of SL-325. SL-425 is currently being evaluated in an ongoing IND-enabling chronic GLP toxicity study, and clinical trials may be conducted in the future. SL-425 may be further developed alongside SL-325 in distinct indications, or to enable extended dosing during maintenance therapy, if necessary, and the need to develop SL-425 will be informed, in part, by the data from the ongoing SL-325 Phase 1 clinical trial.

We are also developing multiple preclinical DR3-based bispecific antibodies which are designed to inhibit both the DR3/TL1A axis and another biologically relevant target for the treatment of patients with IBD or other immune-mediated indications. We plan to disclose the targets of our lead bispecific product candidate, supporting preclinical data, and expected development timelines in the first half of 2026.

The following table highlights our pipeline:



Our Strategy

Our goal is to develop first-in-class immune therapies that improve the quality of life and extend the survival of patients with debilitating and deadly inflammatory and immune-mediated diseases. We plan to achieve this by utilizing our experience in developing TNF receptor agonist and antagonist therapies, our protein design and engineering expertise, and our proven track record of advancing novel biologics into clinical development. Key elements of our strategy include:

- Rapidly advancing SL-325 through clinical development and marketing approval;
- Leveraging our leading position with DR3 blocking antibodies to advance additional bispecific antibody candidates into clinical development;
- Applying our protein engineering and TNF receptor biology expertise to identify, develop, and advance novel biologic compounds in inflammatory and immune-mediated diseases;
- Continuing to augment our internal research and technical operations capabilities;
- Collaborating with leading biopharmaceutical companies;
- Building on our culture of research and development excellence; and
- Deepening our intellectual property portfolio to continue to protect our platform technologies and product candidates.

Our Lead Product Candidate: SL-325

Overview

TL1A (also known as TNFSF15) is a costimulatory ligand in the tumor necrosis factor superfamily, which activates immune responses through binding a single receptor, DR3 (also known as TNFRSF25). TL1A was identified as the ligand for DR3 in 2002, and aberrant activation of DR3 signaling by TL1A has been implicated in a variety of diseases, including UC, CD, hidradenitis suppurativa, psoriatic arthritis, rheumatoid arthritis, asthma, multiple sclerosis, and other inflammatory and immune-mediated diseases. Several single nucleotide polymorphisms (“SNPs”) in TL1A have been shown to significantly increase the risk of humans developing both UC and CD. This genetic linkage contributed to the selection of IBD for initial clinical trials for TL1A blocking antibodies.

Three different TL1A blocking antibodies have demonstrated an improvement in complete remission rates in third-party randomized, placebo controlled, Phase 2 clinical trials in patients suffering from UC and CD. Each of these antibodies (tulisokibart, duvakitug, and afimkibart) have provided placebo-adjusted clinical remission rates of between 23-28% following induction therapy in patients with UC, in trials that included patients who had previously failed biologic therapies. Although a biomarker selection strategy enriching for patients with SNPs in TL1A has been explored, similar rates of clinical response have been observed in patients lacking such SNPs, suggesting that TL1A mediated activation of DR3 contributes to disease pathology regardless of an inborn genetic predisposition. While these data provide clinical validation of the TL1A/DR3 pathway in IBD, we believe that targeting DR3 will provide for greater and more durable efficacy that is achieved by targeting TL1A.

The placebo-adjusted clinical remission rates observed to date with these TL1A blocking antibodies could surpass the monotherapy clinical remission rates observed with anti-TNFα, anti-IL23 and anti-α4β7 blocking antibodies if confirmed in one

or more of the ongoing third-party Phase 3 clinical trials. If confirmed, antibodies targeting the DR3/TL1A signaling pathway could achieve significant commercial penetration in the IBD landscape, which is projected to increase from a $23 billion market in 2023 to a $34 billion market in 2030.

Rationale for Targeting DR3 Instead of TL1A

For certain immune pathways, there is a clear rationale to target either a receptor or ligand because of binding promiscuity. For example, soluble TNFα primarily interacts with TNFR2, whereas TNFR2 can bind lymphotoxin in addition to both soluble and membrane associated TNFα. Other receptor:ligand pairs are selective, including DR3/TL1A, wherein there are no known alternate signaling receptors for TL1A or verified alternate ligands for DR3.

There are significant differences in the tissue localization and expression pattern of TL1A and DR3, which suggest that blocking DR3 may provide more potent inhibition of TL1A mediated DR3 signaling than blocking TL1A. TL1A is an inducible inflammatory ligand mainly expressed by tissue-resident antigen presenting cells, but also endothelial cells. In the absence of inflammation, TL1A is generally not expressed. When innate immune signals, such as bacterial proteins or immune complexes, are present, transcription of TL1A is rapidly induced, peaking within 12 hours and ceasing within approximately 24 hours. This pulse of transcription leads to a wave of TL1A protein expression on the cell membrane, which is then subsequently self-regulated through the presence of a membrane-proximal protease cleavage site, which liberates the extracellular domain from the membrane, thereby limiting its immune stimulatory potential. The cleaved extracellular domain of TL1A can be measured in the blood, and retains the ability to activate DR3. In addition, humans evolved a soluble decoy receptor, DcR3, to neutralize and facilitate degradation of this cleaved TL1A. This pattern of expression explains the relative absence of TL1A on cells found in the blood, and presence of TL1A at sites of active inflammation, but not adjacent non-inflamed tissue.

Whereas TL1A is a short-lived, inducible ligand, DR3 is stably and constitutively expressed, primarily by antigen-experienced lymphocytes. In patients with UC and CD, DR3 is known to be more abundant than TL1A, and to be evenly upregulated both within actively inflamed tissue and the adjacent uninflamed tissue. Complete suppression of TL1A signaling with current TL1A blocking antibodies may be challenging because these antibodies must maintain high local concentrations within tissues by passive diffusion in order to immediately neutralize newly expressed TL1A given the locally high abundance of DR3. In contrast, achieving complete suppression of DR3 signaling may present a lesser challenge due to the stable expression of DR3 by lymphocytes found both in the peripheral blood and throughout the gastrointestinal tract of patients with UC and CD. Given this, we believe that targeting DR3, instead of TL1A, may allow for a more complete and durable blockade of the DR3/TL1A axis, leading to greater efficacy in patients with UC and CD.

One of the natural mechanisms whereby soluble TL1A is degraded is through binding to human protein decoy receptor 3 (“DcR3”). DcR3 neutralizes soluble TL1A, Fas ligand and LIGHT, which all induce a proinflammatory immune response. The extracellular domain of TL1A can be cleaved by specific proteases, leading to release of trimeric TL1A from the surface of immune cells. This soluble form of TL1A can be detected in human blood, where it can then bind to and be degraded by DcR3. Thus, it is desirable to block DR3, but not DcR3, to preserve the natural anti-inflammatory role of DcR3. SL-325 binds to DR3 but not to DcR3.

Another potential advantage of targeting DR3 instead of TL1A relates to the expected immunogenicity profile of each of these agents. High rates of immunogenicity have been observed with current TL1A blocking antibodies in clinical trials. A source of this immunogenicity includes the binding and stabilization of soluble TL1A, leading to substantial increases in the serum concentration of total TL1A in patients following treatment with TL1A blocking antibodies. These immune complexes between anti-TL1A antibodies and soluble TL1A are likely a cause of anti-drug antibody formation in patients, shared by all anti-TL1A antibodies. Because DR3 is a membrane-restricted receptor, and SL-325 was engineered to bind an epitope on DR3 that is not found on DcR3, immune complex formation is not expected with SL-325. Thus, we expect that SL-325 has the potential to demonstrate a best-in-mechanism immunogenicity profile.

We believe that this potential best-in-mechanism immunogenicity profile may translate to improved efficacy. Recent publications have reported that the serum concentration of afimkibart decreases as the concentration of ADA increases. These data demonstrate that ADA are capable of accelerating clearance of TL1A blocking antibodies. In addition, patients whose ADA concentrations remained low had approximately 50% better efficacy than patients whose ADA concentrations were highest. Some ADA are “neutralizing”, indicating that the ADA directly interfere with the ability of an anti-TL1A antibody to bind TL1A. Other ADA are “non-neutralizing”, indicating that the ADA bind to epitopes of the anti-TL1A antibodies that do not directly interfere with TL1A binding. However, it has been shown that both neutralizing and non-neutralizing ADA can reduce efficacy for monoclonal antibodies, such as anti-TNFa antibodies.

SL-325 Antibody Attributes

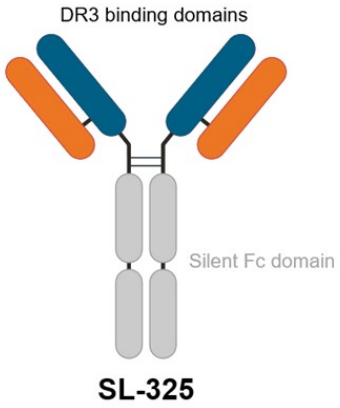
We believe that an ideal DR3 blocking antibody should possess the following attributes:

- Very high affinity binding to DR3;

- Binds to an epitope that is not shared with DcR3;
- Binds to an epitope that does not cause receptor mediated endocytosis of DR3 from the cell surface;
- Directly interferes with the binding of a TL1A trimer to a DR3 trimer; and
- Directly interferes with TL1A mediated trimerization of DR3.

We developed SL-325 with these attributes in mind. SL-325 specifically binds to human DR3 with a 1.3 picomolar affinity and a slow off-rate. Our preclinical studies demonstrate that SL-325 does not cause internalization of DR3, and the combination of a slow off-rate and lack of receptor mediated endocytosis suggests that SL-325 may achieve durable binding to DR3 *in vivo*. The epitope on DR3 bound by SL-325 is not shared with DcR3, and no binding of SL-325 to DcR3 has been observed. This suggests that DcR3 will retain the ability to neutralize and facilitate degradation of soluble TL1A even after patients are treated with SL-325. The design of SL-325 is shown in Figure 1 below.

Figure 1—SL-325 Overview



Preclinical potency assays have demonstrated that SL-325 prevents both the trimer-to-trimer interaction between TL1A and DR3, and the trimerization of DR3 in response to TL1A. Additionally, SL-325 was engineered to lack Fcγ receptor binding to eliminate the potential for antibody mediated cellular cytotoxicity or antibody mediated cellular phagocytosis of DR3 expressing cells.

SL-325 was designed to fundamentally address the therapeutic and DR3/TL1A axis limitations of TL1A blocking antibodies. As a potentially first-in-class DR3 blocking antibody, we believe SL-325 has the desired attributes, demonstrated by our nonclinical studies, necessary to move into clinical development. SL-325 is currently being evaluated in a Phase 1 clinical trial and may emerge as a best-in-mechanism inhibitor of the DR3/TL1A axis due to SL-325's potential to provide a more complete and durable blockade of DR3 signaling than is achievable with TL1A blocking antibodies, and with a best-in-mechanism immunogenicity profile.

Preclinical Experience

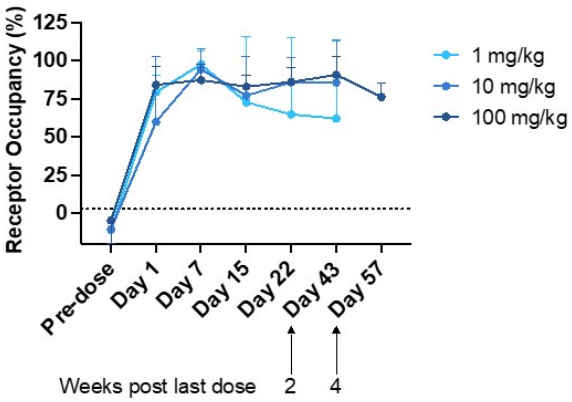
GLP Non-Human Primate Studies

We conducted an acute, IND-enabling GLP toxicology study with SL-325 in NHPs, evaluating safety, tolerability, PK, and immunogenicity. These data were shared at the 20th Congress of the European Crohn's and Colitis Organization on February 20, 2025.

Naïve cynomolgus macaques each received three doses of intravenous SL-325 (vehicle, 1 mg/kg, 10 mg/kg or 100 mg/kg dose groups), with each dose administered two weeks apart. No infusion related reactions, changes in serum chemistry values, or evidence of other toxicities or organ dysfunction (by gross or histopathology) were observed. The No Observed Adverse Effect Level from this GLP toxicology study was determined to be the top dose administered dose of 100 mg/kg. As shown in Figure 2 below, full and durable DR3 RO was observed in peripheral blood lymphocytes at doses of 1 mg/kg or higher within two hours of infusion, throughout the 14-day inter-dose interval (all dose groups), and for the 28-day interval for the animals in

the recovery group (100 mg/kg dose level). Following administration of SL-325, we observed no proliferation or activation of DR3 expressing CD4+ or Treg cells, confirming a lack of agonism of DR3.

Figure 2—SL-325 Receptor Occupancy in NHP Study



PK data collected in the NHP study was used to generate a population PK model to predict SL-325 exposure in humans at different dose levels and dosing intervals. Data collected from our GLP NHP study suggest that 1 µg/mL trough concentrations are required to maintain full RO on peripheral blood lymphocytes. Population PK models suggest that 1 µg/mL trough concentrations are likely to be exceeded if SL-325 is administered at the 3 mg/kg dose level, every eight weeks during the maintenance phase of treatment. We are further characterizing the PK profile in humans in our ongoing Phase 1 clinical trial, which will further inform on the dose and dosing schedule to be advanced into Phase 2 clinical trials. Our goal is to select a dose and dosing schedule that maintains SL-325 concentrations in human peripheral blood which exceeds the threshold required to maintain full DR3 receptor occupancy both in peripheral blood and within affected tissues. We believe that SL-325 can achieve Q4W dosing during induction, and maintenance dosing no more frequently than once monthly.

In summary, our in vitro functional activity and GLP NHP toxicology study results indicate SL-325 is a high-affinity DR3 blocking antibody, with no evidence of toxicity or residual agonism in cynomolgus macaques. Additional data gathered from the NHP study suggests that full DR3 RO was maintained when the serum concentration of SL-325 remained above approximately 1 µg/mL, and when combined with SL-325's PK profile, we believe are supportive of prolonged dosing intervals in human patients.

We are also currently conducting a six-month, chronic GLP toxicology study of SL-325 (and SL-425) in NHPs, evaluating safety, tolerability, PK, and immunogenicity. We expect to complete the study in the first quarter of 2026, and we plan to share the data in the second quarter of 2026. To date, both SL-325 and SL-425 have been well tolerated, with no drug-related adverse events or infusion-related reactions observed. SL-425 has demonstrated the expected half-life extension in comparison to SL-325. As was the case in our acute GLP toxicology studies, no evidence of DR3 agonism has been observed in any animal at any dose at any time. This study has enabled extended observation periods for the durability of DR3 occupancy, and durable binding has been observed for at least 71 days. Both SL-325 and SL-425 have demonstrated a favorable immunogenicity profile following repeated dosing in the chronic toxicology study, similar to the prior profile of SL-325 observed in the acute toxicology study.

Preclinical In-Vitro Characterization

We characterized the DR3 binding and antagonistic properties of SL-325 in a series of *in vitro* assays and these data were presented in a poster at the Crohn's & Colitis Congress 2025 Annual Meeting on February 7, 2025.

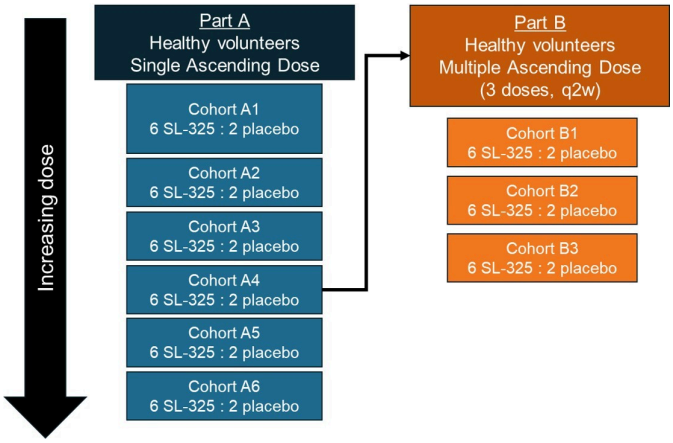
Clinical Development

Phase 1 Clinical Trial in Healthy Volunteers

We are currently conducting a randomized, double-blind, placebo-controlled SAD/MAD Phase 1 clinical trial in healthy volunteers to evaluate the safety, tolerability, pharmacokinetics, and immunogenicity of SL-325, and to establish the Phase 2 dose and dosing schedule.

In this Phase 1 clinical trial, we plan to evaluate up to six escalating dose levels of SL-325 in the SAD portion of the trial, and up to three dose levels of SL-325 in the MAD portion of the trial. We plan to enroll a total of approximately 72 healthy volunteers. Each cohort will be randomized, with six volunteers receiving SL-325 and two volunteers receiving placebo. Volunteers in the MAD portion of the trial will receive three doses, administered on days 1, 15, and 29. Figure 3 below illustrates a design schema of this Phase 1 clinical trial.

Figure 3—SL-325 SAD and MAD Phase 1 Clinical Trial Design



Phase 2 Clinical Development Plans and Strategy

Upon completion of our Phase 1 clinical trial, we plan to initiate a randomized, double-blinded, placebo-controlled Phase 2 clinical trial evaluating SL-325 in patients with CD. We plan to evaluate two dose levels of SL-325 versus placebo, and will provide additional details of the clinical trial design in the second quarter of 2026. We anticipate initiating this clinical trial in the third quarter of 2026.

Research Programs

We maintain a strong research organization that has developed a diverse pipeline of preclinical compounds. One of our guiding principles for considering additional pipeline candidates is a preference for compounds that we expect to have monotherapy activity early in clinical development.

DR3 Bispecific Antibodies

In addition to SL-325 and SL-425, we are developing a series of bispecific antibodies targeting DR3 and other clinically validated targets. The future of biologic therapy for both UC and CD is widely believed to include blockade of multiple inflammatory pathways, and the mechanism of DR3/TL1A inhibition is known to be non-redundant with the mechanism of other clinically validated targets.

Several attempts have been made to develop bispecific antibodies targeting TL1A, including a TL1A and TNFα blocking antibody known as AMG966. As discussed above, TL1A blocking antibodies stabilize serum TL1A as a result of immune complex formation between soluble TL1A and anti-TL1A antibodies. These immune complexes are believed to contribute to the high rates of ADA formation with TL1A blocking monoclonal antibodies. In the case of AMG966, the bispecific antibody was shown to stabilize both soluble TL1A and TNFα, which led to large immune complex formation and the rapid development of high-titer neutralizing ADA responses in patients treated in a third-party Phase 1 clinical trial. AMG966 was discontinued as a result of this immunogenicity. A second TL1A directed bispecific antibody, RO7837195, targets TL1A and IL-23 p40. This antibody was also tested in a third-party Phase 1 clinical trial in healthy volunteers. Like AMG966, RO7837195 also induced ADA in nearly 100% of treated subjects after a single dose, and most of these ADA were also neutralizing. These two clinical trials suggest high rates of ADA may be unavoidable for TL1A-directed bispecific antibodies. The emerging clinical data for TL1A-directed bispecific antibodies is similar to the prior failure of multiple TNFα-directed bispecific antibodies. Both TNFα and TL1A are soluble trimeric proteins, and binding of bispecific antibodies to these proteins is known to cause large immune complex formation which results in the formation of ADA in nearly all treated subjects. Because DR3 is a membrane-restricted target, immune complex formation is not expected either for SL-325, SL-425, or DR3 directed bispecific antibodies.

Manufacturing and Supply

By working with third-party vendors to conduct activities in compliance with current Good Manufacturing Practices ("cGMP"), we have invested significant resources to identify and scale up a suitable manufacturing process for our product candidates, including SL-325. Currently, SL-325 is produced by mammalian cell lines commonly used in the manufacture of monoclonal antibodies, including Chinese hamster ovary cells.

We manufacture bulk drug substance ("BDS") for SL-325 utilizing the services of a single third-party contract manufacturer, Kemwell Biopharma Private Limited ("Kemwell"), with whom we maintain a master service agreement, pursuant to which Kemwell manufactures BDS on a per project basis. We may terminate the master services agreement at any time for convenience in accordance with the terms of the agreement. Either party may also terminate the master services agreement with respect to an uncured breach by the other party in accordance with the terms of the agreement. This agreement includes confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We expect to continue to devote significant resources to process development and optimization of the manufacture of our product candidates, including SL-325, SL-425, and potential DR3-based bispecific antibodies.

All of our product candidates are manufactured from a master cell bank of that protein's production cell line. We have or intend to have one master cell bank for each product candidate that was or will be produced and tested in accordance with cGMP and applicable regulations. Each master cell bank is or will be stored in two independent locations, and we intend to produce working cell banks for each product candidate later in product development. It is possible that we could lose multiple cell banks from multiple locations and have our manufacturing severely impacted by the need to replace the cell banks. However, we believe we have adequate backup should any particular cell bank be lost in a catastrophic event.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing, and commercialization of therapies for immune-mediated diseases, including IBD. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that develop therapies for immune-mediated diseases. There are many other companies that have commercialized or are developing therapies for immune-mediated diseases, including large pharmaceutical and biotechnology companies, such as Abbvie, Johnson & Johnson, Merck, Novartis, Pfizer, Roche/Genentech, Sanofi, Teva and Takeda.

With respect to our lead product candidate, SL-325, we are aware of other clinical-stage therapeutics that target the TL1A/DR3 axis, including, but not limited to, the following TL1A targeting antibodies: duvakitug in development by Teva Pharmaceutical Industries Ltd., ABBV-701/FG-M701 in development by Abbvie/FutureGen Biopharmaceutical Co., Ltd., afimkibart in development by Hoffmann-La Roche Ltd, SPY002 and SPY072 in development by Spyre Therapeutics, Inc., tulisokibart in development by Merck & Co., Inc., and XmAb942 in development by Xencor, Inc. ABS-101 was another half-life extended TL1A blocking antibody previously in development by Absci Corporation. We are not aware of any companies with publicly disclosed DR3 targeted blocking antibodies.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. 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, establishing clinical trial sites and manufacturing capacity and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity 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 or our collaborators may develop. Our competitors also may obtain U.S. Federal Food and Drug Administration ("FDA") or foreign 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 or our collaborators are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their

efficacy, safety, convenience, price, the effectiveness of companion diagnostics, if required, the level of biosimilar or generic competition, and the availability of reimbursement from government and other third-party payors.

Intellectual Property

We strive to protect and enhance our proprietary technology, inventions, and improvements that we consider commercially important to the development of our business, including by seeking, maintaining, and defending U.S. and foreign patent rights, including patents covering our platform technologies, product candidates, and methods of using the same, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, and continuing technological innovation to develop, strengthen and maintain our proprietary position in our field. Additionally, we intend to rely on regulatory protection afforded through data exclusivity and market exclusivity, among others, as well as patent term extensions, where available.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business, including our platform technologies and product candidates, defend and enforce our intellectual property rights, in particular our patents rights, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating, or violating the valid and enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology companies like ours are generally uncertain and can involve complex legal, scientific, and factual issues. We cannot predict whether the patent applications we are currently pursuing, or those we will file or license from others, will grant us patents in any particular jurisdiction or whether the claims of any granted patents will provide sufficient proprietary protection from competitors.

In addition, the coverage claimed in a patent application may be significantly reduced before a patent is granted, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented, or invalidated by third parties. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. See “Risk Factors—Risks Related to Intellectual Property and Information Technology” for a more comprehensive description of risks related to our intellectual property.

For any individual patent, the term depends on the applicable law in the country in which the patent is granted. In most countries where we have filed patent applications or in-licensed patents and patent applications, patents have a term of 20 years from the application filing date or earliest claimed nonprovisional priority date. In the United States, the patent term is 20 years from the application filing date or earliest claimed nonprovisional priority date, but may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may also be lengthened by a Patent Term Adjustment in order to address administrative delays by the U.S. Patent and Trademark Office (“U.S. PTO”) in granting a patent.

In the United States, the term of a patent that covers an FDA-approved drug or biologic may be eligible for Patent Term Extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension of up to five years beyond the natural expiration of the patent (but the total patent term, including the extension period, must not exceed 14 years following FDA approval). The term extension period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO reviews and approves the application for any Patent Term Extension in consultation with the FDA. In the future, we may decide to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant biologics license application.

We generally file patent applications directed to our key technologies and programs in an effort to secure our intellectual property positions. As of February 20, 2026, we own two issued U.S. patents, four pending international patent applications, filed under the Patent Cooperation Treaty, and one pending non-provisional patent application, filed in the United States, that relate to DR3. We also own or exclusively license other patents and patent applications related to other technologies and

programs, including legacy programs. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. PTO and other patent offices may be significantly revised before issuance, if granted at all.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, or a small molecule drug candidate's quality, safety and efficacy, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our company and our products or product candidates.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current GLP regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with cGMPs;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application ("BLA"), after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls

are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and

- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial 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 or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the IND submission process, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment and such review may result in some delay before initiation of a clinical trial.

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

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

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

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

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

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

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

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

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted except that the PREA will apply to an original BLA for a new active ingredient that is orphan-designated if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, 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 may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any

requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("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

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

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. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted 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.

In 2017, the FDA established a new regenerative medicine advanced therapy ("RMAT") designation as part of its implementation of the 21st Century Cures Act ("the Cures Act"). The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (i) the drug qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the

FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. When appropriate, the FDA can permit fulfillment of post-approval requirements for an RMAT that has received accelerated approval through: the submission of clinical evidence, preclinical studies, clinical trials, patient registries or other sources of real world evidence such as electronic health records; the collection of larger confirmatory datasets; or post-approval monitoring of all patients treated with the therapy prior to approval.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if there is evidence it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, 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 (as compared to ten months under standard review).

Fast track designation, breakthrough therapy designation, RMAT designation and priority review do not change the standards for approval but may expedite the development or approval process. 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 or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

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

There is some uncertainty with respect to the FDA's interpretation of the scope of orphan drug exclusivity. Historically, exclusivity was specific to the orphan indication for which the drug was approved. As a result, the scope of exclusivity was interpreted as preventing approval of a competing product. However, in 2021, the federal court in Catalyst Pharmaceuticals, Inc. v. Becerra suggested that orphan drug exclusivity covers the full scope of the orphan-designated "disease or condition" regardless of whether a drug obtained approval for a narrower use.

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 record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics. 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 the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, 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 cGMPs 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 cGMPs 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 adverse events 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, complete withdrawal of the product from the market or product recalls;
- fines, warning 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;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. 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.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to

or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. The FDA has issued guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Patent Term Extension

In the United States, after a BLA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of a BLA, plus the time between BLA submission date and the BLA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process,

failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common commercial activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, for persons in a position to refer or recommend federally reimbursable healthcare business may be alleged to be intended to induce prescribing, purchasing or recommending, and may be subject to scrutiny if they do not qualify for an exception or regulatory safe harbor. Qualifying for a statutory exception or regulatory safe harbor requires satisfying all of the criteria for the exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory 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 AKS, but it does increase the risk of regulatory scrutiny. Ultimately, 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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The FCA, which can be enforced through civil whistleblower or qui tam actions, prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act.

We are also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we

may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners.

For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations impose data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information ("PHI") for or on behalf of such covered entities. These requirements imposed by HIPAA and HITECH on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and 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. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, that govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state attorneys general, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The CCPA and numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, exempt PHI that is subject to HIPAA; and others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence and machine learning, controlling for data bias, and anti-discrimination.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

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

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, 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 or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a

list of 15 additional Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar's market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain. In addition, net 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 U.S. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price 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.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, 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.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress. In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state

measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In May 2025, the Trump Administration renewed the idea of international reference pricing through an executive order entitled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which, among other things, directs the HHS and other agencies to communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for U.S. patients in line with comparably developed nations and to facilitate direct-to-consumer purchasing programs. The HHS subsequently issued guidance indicating the MFN target price will be the lowest price paid in an Organisation for Economic Co-operation and Development country with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capital. In addition, in December 2025, CMS proposed new drug payment models to lower drug prices for Medicare beneficiaries; under the models, CMS would explore potential adjustments to Medicare drug inflation rebate calculations by comparison to international drug pricing information. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect government authorities to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Individual states in the U.S. have also become 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 drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for its drugs or put pressure on its drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The processing of personal data, including health-related personal data, in the European Economic Area ("EEA") is mainly governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("GDPR"), and related data protection laws in individual EEA countries. In the United Kingdom, the processing of personal data is mainly governed by the GDPR as incorporated into UK law pursuant to the European Union (Withdrawal) Act 2018 (the "UK GDPR"). The

GDPR and UK GDPR impose a number of strict obligations and requirements for the processing, including collecting, analyzing and transferring, of personal data of individuals in the EEA or in the UK, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR and UK GDPR include requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and obligations relating to the security and confidentiality of the personal data. EEA countries may also impose additional requirements in relation to the processing of health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EEA that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on the appropriate safeguards, data exporters, with the assistance of the data importers, are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the safeguards in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework.

With regard to the transfer of data from the EEA to the UK, based on the EC's adequacy decision of June 28, 2021 and subsequent renewals, personal data may continue to flow freely from the EEA to the UK on the basis that the UK is deemed to provide an adequate level of data protection until December 27, 2031. The adequacy decisions will automatically expire unless renewed.

With respect to transfers from the UK to other countries, these transfers are also subject to specific transfer rules under the UK regime. These UK international transfer rules broadly mirror the EU GDPR rules.

On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers ("UK Addendum") and a document setting out transitional provisions. The IDTA and UK Addendum came into force on March 21, 2022 and are the primary UK-approved mechanisms for putting in place appropriate safeguards for UK restricted transfers, subject to transitional arrangements for legacy SCCs. Regarding transfers from the UK to the EEA, the UK Information Commissioner's Office ("ICO") guidance indicates that organizations do not need new arrangements. With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the UK Extension to the EU-US Data Privacy Framework, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the recipient is a U.S. organization certified to the EU-US Data Privacy Framework and participating in the UK Extension to the EU-US Data Privacy Framework.

Failure to comply with the requirements of the GDPR or UK GDPR and the related national data protection laws of the EEA countries may result in significant monetary fines for noncompliance of up to €20 million or £17.5 million (as applicable), 4% of the total worldwide annual turnover (for higher-tier infringements). This is enforced by ICO and is entirely separate from fines under EU GDPR. In addition, violations of national laws can trigger additional, administrative penalties, investigations, corrective orders, temporary or definitive bans, and, in some jurisdictions, and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed.

Data protection authorities from the different EEA countries may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EEA.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU Clinical Trials Regulation No. 536/2014 ("CTR"), European Medicines Agency ("EMA") disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization ("MA") for human medicines in the EU/EEA must have been carried out in accordance with EU regulations. This means that clinical

trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EEA, including adhering to international good clinical practice and the Declaration of Helsinki. The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC, ("Clinical Trials Directive") and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the CTR, a sponsor is able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the "Clinical Trials Information System" or "CTIS"). One national regulatory authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application consult and coordinate with the other concerned EU Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU Member States. However, a concerned EU member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU database, including a layperson's summary. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory and CTIS serves as the single entry point for submission of clinical trial-related information and data. As of January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive need to comply with the CTR and have to be transitioned to CTIS.

Under the CTR, national laws, regulations, and the applicable GCP and GLP standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on GCP and the ethical principles that have their origin in the Declaration of Helsinki. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the National Competent Authority and to the Ethics Committees of the EU member state where they occur.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working PartyCA. A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain an MA of a drug under European Union regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

To be used or sold in the UK, a drug must have an effective MA granted by the Medicines and Healthcare Products Regulatory Agency (MHRA) under the Human Medicines Regulations 2012 (SI 2012/1916), as amended. MA applications are submitted electronically via the MHRA Submissions Portal. Under the MHRA's national assessment procedure, the MHRA generally aims to reach a decision within 210 "clock-on" days, excluding any "clock-stops" while the applicant prepares responses to MHRA questions.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Recognition Procedure ("IRP") for MAAs. The IRP applies since January 1, 2024 and replaces existing EU reliance procedures to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows medicinal products approved in other jurisdictions that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the European Medicines Agency ("EMA") that is valid for all EU Member States as well as in the three additional EEA Member States (Norway, Iceland, and Liechtenstein). The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy, or tissue engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and

indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

Under the centralized procedure, the CHMP is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure

Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization: (i) they can be authorized under the centralized procedure if they concern a significant therapeutic, scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state; or (iii) they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national MA (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned member states, are subsequently required to grant a MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA, subject only to limited redactions.

MA Validity Period

MAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA. Following Windsor Framework changes, which became effective January 1, 2025, European Commission Union authorizations are no longer valid in Northern Ireland and centrally authorized products are instead authorized by the MHRA under UK-wide marketing authorizations; existing licenses for product licensed by the MHRA that covers Great Britain only become geographically valid UK-wide while retaining their license number/prefix.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on December 31, 2020 (the "Brexit

Transition Period") will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining member states of the EU, the three year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including advanced therapy medicinal products ("ATMPs") are subject to extensive pre-and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to Regulation (EC) No 1394/2007, the Committee for Advanced Therapies (CAT) is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Exceptional Circumstances/Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU in exceptional circumstances. A conditional MA can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. Once a conditional MA has been granted, the MA holder must fulfill specific obligations within defined timelines. A conditional MA is valid for one year and must be renewed annually, but it can be converted into a standard MA once the MA holder fulfills the obligations imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. Innovative medicinal products, referred to as New Chemical Entities ("NCE"), approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product's first MA in the EU. After eight years, a generic product application may be submitted, and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one-year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the EU's regulatory authorities to include a NCE. Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product

if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation and negotiations are still ongoing. The timing for finalization of these negotiations and entry into force are unclear.

The current drafts envisage:

- a shortening of the periods of data exclusivity from eight to six years (with transferrable vouchers for an additional year of market protection as an incentive for the development of new antibiotics),
- earlier regulatory guidance and extension of market exclusivity for orphan medicines (depending on certain conditions),
- four-year data exclusivity for additional indications of existing products, and
- rules governing the availability of products (including shortage prevention plans and some supply obligations for manufacturers).

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. The EMA grants orphan drug designation if the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU (prevalence criterion). In addition, Orphan Drug Designation can be granted if, for economic reasons, the medicinal product would be unlikely to be developed without incentives and if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. An application for orphan drug designation (which is not a MA, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for MA of the medicinal product is submitted. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MA is submitted, and sponsors must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional MA.

The EMA's Committee for Orphan Medicinal Products reassesses the orphan drug designation of a product in parallel with the review for a MA; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of MA review by the EMA and approval by the EC. Additionally, any MA granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of a MA, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, the regulatory authorities of the EU Member States and the EMA may not accept applications for MA accept an application to extend an existing MA or grant a MA for other similar medicinal products for the same therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity for an orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics ("SmPC") addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, i.e. the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a MA may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

In the UK, following the post-Brexit transition period, a system for incentivizing the development of orphan medicines was introduced. Overall, the requirements for orphan designation largely replicate the requirements in the EU and the benefit of market exclusivity has been retained. Products with an orphan designation in the EU can be considered for an orphan MA in Great Britain and, marketing authorizations granted for products that fulfill UK orphan criteria are valid UK-wide regardless of whether there is an EU orphan designation. The MHRA will review applications for orphan designation at the time of a MA, and will offer incentives, such as market exclusivity and full or partial refunds for MA fees to encourage the development of

medicines in rare diseases. Separately, the MHRA has stated that it is considering updating its licensing framework for orphan medicines, with a draft framework expected by spring 2026.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has published guidance on the procedures for UK Paediatric Investigation Plans ("PIPs") which, where possible, mirror the submission format and requirements of the EU system. From January 1, 2025, EU pediatric requirements are addressed via Windsor Framework categorization: for Category 2 products, both UK and EU pediatric requirements apply, and an EU-agreed PIP must also be in place (unless waived).

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small-and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from CAT are appointed facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and MAs. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of a MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of Periodic Safety Update Reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

On October 27, 2025, the Council of the European Union approved a framework for compulsory licensing of crisis-relevant products (including medicinal products) in crisis situations. While the proposal focuses on voluntary agreements with intellectual property rights holders, it includes rules on compulsory licensing as a measure of last resort upon activation / declaration of a crisis or emergency mode. The European Parliament has not yet voted on the proposal.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the MA granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals. EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the Human Medicines Regulations. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK-based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual

EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed.

The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offense committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 (the "MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Regulation

In addition to the foregoing, local, state and federal laws, including in the United States and Israel, regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control 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 or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws 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. We may incur significant costs to comply with such laws and regulations now or in the future.

Human Capital Management

As of December 31, 2025, we employed 40 full-time employees at two locations in the United States, in Austin, TX and Durham, NC.

We may hire additional employees in 2026 and beyond with a focus on increasing expertise and bandwidth in clinical research and development, in-house process development and manufacturing, and clinical operations to support potential later-stage clinical trials. We continue to evaluate business needs and opportunities, with a hiring philosophy that seeks to balance in-house expertise with outsourced services, and management of overall operating expense. Currently, we outsource clinical trial work to clinical research organizations and drug manufacturing to contract manufacturers.

Drug development is a complex endeavor which requires deep expertise and experience across a broad array of disciplines. Pharmaceutical companies compete for a limited number of highly qualified applicants to fill specialized positions. To attract these applicants to the Company, we offer a total rewards package consisting of a base salary and cash target bonus targeting the 25th to 75th percentile of market based on geography, a competitive benefit package and equity compensation for full-time employees. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility.

We believe our management team has the experience necessary to effectively execute our strategy and advance our product and technology leadership. A large majority of our employees have obtained advanced degrees in their professions. We support our employees' further development with individualized development plans, mentoring, coaching, group training and conference attendance.

Corporate Information

We were incorporated in Delaware in May 2016. Our corporate offices are located at 500 W. 5th Street, Suite 1200, Austin, Texas 78701 and 21 Alexandria Way, Suite 200, Durham, North Carolina 27713 and our telephone number is (512) 900-4690. Our website address is www.shattucklabs.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is for convenience only and the information on the referenced website does not constitute a part of nor is incorporated by reference into this report.

Our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including our annual reports on Form 10-K, our quarterly reports on Form 10-Q and our current reports on Form 8-K, and amendments to those reports, are accessible through our website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the Securities and Exchange Commission (the "SEC"). These SEC reports can be accessed through the "Investors" section of our website.

Item 1A. Risk Factors

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Annual Report on Form 10-K and in our other filings with the SEC before making an investment decision. The occurrence of any of the following risks could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future.

Summary of Key Risk Factors

- We are an early clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale, have never generated revenue from product sales, and may never achieve or maintain profitability.
- We will require additional funding in order to complete development of our product candidates including SL-325, and commercialize our products, if approved. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs and current and future clinical trials, our efforts to access manufacturing capacity, and any commercialization efforts.

- Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.
- We have not completed any late-stage clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We are substantially dependent on the success of our lead product candidate, SL-325, and our current and any future clinical trials of such product candidate may not be successful.
- Our product candidates are in preclinical and clinical stages of development and may fail in development or suffer delays. We depend on the successful initiation and completion of clinical trials for our product candidates to advance our product development plans.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit both the scope of regulatory approval and our ability to successfully commercialize.
- Preclinical and clinical development is a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If preclinical studies and clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and, therefore, be unable to complete the development of and commercialize our product candidates on a timely basis or at all.
- We may not be successful in our efforts to identify or discover additional product candidates.
- We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.
- Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval.
- If we experience delays or difficulties initiating clinical trial sites or enrolling patients in our planned clinical trials, our research and development efforts, business, financial condition, and results of operations could be materially and adversely affected.
- The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis, if at all, our business will be substantially harmed. We operate in highly-competitive and rapidly-changing industries, which may result in others discovering, developing, or commercializing competing products before or more successfully than we do.
- We rely on third parties to supply raw materials and to manufacture our product candidates. The manufacture of our product candidates is complex and our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.
- Our success depends upon our ability to obtain and maintain patents and other intellectual property rights to protect our technology, including SL-325, methods used to manufacture our product candidates, formulations thereof, and the methods for treating patients using those product candidates.
- Economic downturns, inflation, fluctuating interest rates, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, natural disasters, public health crises such as pandemics or other events could materially and adversely affect our business operations, workforce, product development activities, research and development activities, preclinical and clinical trials, and financial condition.

Risks Related to Our Business, Our Financial Condition and Capital Requirements

We are an early clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale, have never generated revenue from product sales, and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company and will need to raise substantial additional capital to continue to fund our operations in the future. We have based our estimates on assumptions that may prove to be wrong, and could exhaust our available financial resources sooner than we currently anticipate.

Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant operating losses since inception. For the years ended December 31, 2025 and 2024, we reported a net

loss of $48.8 million and $75.4 million, respectively. As of December 31, 2025, we had an accumulated deficit of $430.5 million. We expect to continue to incur significant operating losses for the foreseeable future, including as our product candidates continue through preclinical and clinical development. We expect to invest significant funds into the research and development of our current programs to determine the potential to advance product candidates to regulatory approval. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We may never succeed in these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our lead product candidate, SL-325;
- continue the preclinical development and initiate the clinical development of our potential bispecific product candidates and any other potential product candidates, including SL-425;
- continue efforts to discover and develop new product candidates;
- continue the manufacturing of our product candidates or increase volumes manufactured by third parties;
- initiate additional preclinical and nonclinical studies or clinical trials for our product candidates;
- seek regulatory and marketing approvals for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which it may obtain marketing approval and market for ourselves;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with the development and potential regulatory approval of our clinical and product candidates such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

We will require additional funding in order to complete development of our product candidates, including SL-325, and commercialize our products, if approved. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs and other operations.

Based on our current business plans, we estimate that our existing cash and cash equivalents and short-term investments, assuming the full exercise of our outstanding common stock warrants, will enable us to fund our operations into 2029. We have based this estimate on assumptions that may prove to be wrong, including that the outstanding common stock warrants will be exercised in full, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned through public or private equity or debt financings or other sources, such as strategic collaborations. 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. Attempting to secure additional financing may divert our management from our day-to-day activities, which may materially and adversely affect the development of our product candidates. Our ability to raise additional funds will depend on financial, economic, and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us or at all.

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

If we raise additional capital through the sale of equity, including through our "at-the-market" offering facility (the "ATM Facility"), or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends, which could materially and adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our 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 or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate

our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates and related technologies. Although we have employment agreements with certain of our key employees, including our Chief Executive Officer, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice.

In the future, as we progress SL-325, and any other current or future product candidates through clinical development, we expect to experience periods of growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical operations, business development, manufacturing, regulatory affairs, quality assurance, human resources, legal, accounting and finance, and, ultimately, sales and marketing. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical, and managerial employees. If our recruitment and retention efforts are unsuccessful, when needed, in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

To manage any future growth, we must continue to implement and improve our managerial, operational, and financial systems, and expand our facilities. Due to our limited financial resources and the limited experience of our management team in managing a growing company, we may not be able to effectively manage the expansion of our operations systems and facilities. These activities may lead to significant costs and may divert our management and other resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, we are a small company with limited resources, our business prospects are uncertain, and our stock price is volatile. For some or all of the foregoing reasons, we may not be able to recruit all of the management, technical, and other personnel that we require or we may be unable to retain all of our existing personnel. In such event, we may be required to limit our growth and expansion efforts and our business and financial results may suffer.

We have not completed any late-stage clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since our inception in 2016, we have devoted a significant portion of our resources to developing our product candidates, our other research and development efforts, building our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete product development activities, complete late-stage clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you or we may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Risks Related to the Development and Clinical Testing of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, SL-325, and our current and any future clinical trials of such product candidate may not be successful.

Our lead product candidate, SL-325, is in a Phase 1 clinical trial, and if that product candidate is not successful, our business could be materially impacted. While we have other preclinical programs, such as SL-425, there is no guarantee that these programs will advance into clinical development. Our future success is substantially dependent on our ability to develop and timely obtain marketing approval for, and then successfully commercialize, SL-325. We are investing the majority of our efforts and financial resources into the research and development of SL-325, SL-425, and other DR3 based bispecific antibodies targeting DR3 together with another biologically relevant target.

Our product candidates, including our lead product candidate, SL-325, are in the early stages of development and will require substantial preclinical and clinical development and testing, manufacturing process development, improvement and validation, and regulatory approval prior to commercialization and before we generate any revenues from product sales. The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator.

Of the large number biologics and drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a biologics license application ("BLA") to the FDA or marketing authorization application ("MAA") to the European Medicines Agency ("EMA"), and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market any of our product candidates, any such approval may be subject to limitations on the indicated uses for which we may market the product, or limitations related to its distribution, or be conditional on future development activities and clinical results. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, there can be no assurance that any of our product candidates will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain regulatory approval, or, if approved, successfully commercialize, any of our product candidates, we may not be able to generate sufficient revenue to continue the operation of our business.

SL-325 is in early stages of clinical development and our other product candidates are in preclinical stages of development, and any of our product candidates may fail in development or suffer delays. We depend on the successful initiation and completion of clinical trials for our product candidates to advance our product development plans.

We have no products on the market, and our product candidates are in early clinical and preclinical stages of development. As a result, we expect it will be years before we can obtain regulatory approval for and commercialize any product candidate, if ever. We must complete clinical trials that demonstrate the safety and efficacy of our product candidates in humans, and we do not yet know if our lead product candidate, SL-325, will be safe or effective in humans. Clinical testing is expensive, difficult to design and implement, and can take years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Preclinical and clinical development is a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results. If preclinical studies and clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and, therefore, be unable to complete the development of and commercialize our product candidates on a timely basis or at all.

It is impossible to predict when or if any of our product candidates will prove safe and effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure can occur at any time or stage of the preclinical study or clinical trial process. Additionally, there is no guarantee that our future IND filing(s), or amendments to our existing INDs, will be accepted by the FDA, or comparable foreign regulatory authorities, or that these filings(s) will be accepted within our expected timelines. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product candidate, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their compounds and product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the independent institutional review boards of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or are only moderately positive, or if there are safety concerns, our business and results of operations may be materially and adversely affected, and we may incur significant additional costs.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent, delay or limit both the scope of regulatory approval and our ability to successfully commercialize.

To obtain the requisite regulatory approvals to market and sell any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our compounds and investigational drug products are safe and effective for use in each targeted indication in humans. Clinical testing is expensive and takes many years to complete, and its outcome is inherently uncertain. The process of obtaining regulatory approval is expensive, often taking many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency.

Clinical trials that we conduct may not demonstrate the efficacy and safety that is necessary to obtain regulatory approval to market our product candidates. If the results of our future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. For example, with respect to a legacy product candidate, SL-172154, we previously discontinued development when promising complete remission rates from interim data did not translate into improved overall survival in subsequent topline data. Additionally, any safety concerns observed in any one of our future clinical trials could limit the prospects for regulatory approval of that product candidate or other product candidates in any indications. Even if our clinical trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we are able to submit our product candidates for approval. Moreover, results that are acceptable to support approval in one jurisdiction may be deemed inadequate to support regulatory approval in other jurisdictions. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate in a manner that does not meet our expectations, which limitations may reduce its commercial potential.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products. Our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to lack efficacy, have harmful side effects, or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that may ultimately prove to be unsuccessful.

We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.

The development and commercialization of drugs is highly competitive. Product candidates developed by us, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of biopharmaceutical companies as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals, and marketing than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. 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, establishing clinical trial sites, recruiting participants for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

Our competitors have developed, are developing or will develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have competitive safety, efficacy, dosing and/or presentation profiles. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing programs which may compete with one another. For example, we are developing SL-325 and may choose to develop SL-425, and/or a potential DR3-based bispecific antibody, for the same indication: inflammatory bowel disease, and may in the future develop our programs for other inflammatory and immune-mediated diseases. Developing multiple programs for a single indication may negatively impact our business if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple programs are approved for the same indication, they may compete for market share, which could limit our future revenue.

Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval and our ability to market and derive revenue from our product candidates could be compromised.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Our product candidates, including our lead product candidate, SL-325, have not completed any clinical trials in humans, and we do not yet know if it will have serious, undesirable, or unacceptable side effects. Results of our preclinical studies or clinical trials could reveal a high and unacceptable severity and/or prevalence of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition and results of operations.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

If we experience delays or difficulties initiating clinical trial sites or enrolling patients in our planned clinical trials, our research and development efforts, business, financial condition, and results of operations could be materially and adversely affected.

We have not yet completed any clinical trials for our product candidates, including our lead product candidate, SL-325. Successful and timely completion of our planned clinical trials will require that we initiate our clinical trial sites in a timely manner and enroll a sufficient number of subjects or patients. Trials may be subject to delays for a variety of reasons, including as a result of delays to clinical trial site start up and initiation, patient enrollment taking longer than anticipated, fewer than expected patients who meet enrollment eligibility criteria, patient withdrawal, or AEs. Our clinical trials may compete with other clinical trials that are in the same therapeutic areas as our product candidates and/or that seek to enroll the same specific patient populations as our clinical trials, which reduces the number and types of patients available to us. We may also compete with head-to-head clinical trials, in which patients may prefer to participate, which may further reduce the number of patients available to us.

If we are unable to initiate or adequately enroll our clinical trial sites, our clinical trials may be delayed. Receiving approval for and establishing clinical trial sites in other countries may be more challenging or lengthy than in the United States. As a result of any of the aforementioned factors, we may in the future decide to use clinical trial sites in other parts of the world. It may be more difficult to control international clinical trials and the results may be less reliable. In addition, if the international clinical trial was conducted in a country with lower quality healthcare than in developed countries, the patients may experience side effects not experienced by patients in developed countries.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial resources, we focus our research and development efforts on certain selected product candidates, including SL-325. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development

programs and product candidates for specific indications may not yield any commercially viable product candidates. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may 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.

Risks Related to Our Regulatory Environment

The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis, if at all, our business will be substantially harmed.

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 product candidates are subject to extensive regulation by the FDA and by comparable regulatory authorities outside the United States. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other application for marketing approval. This lengthy approval process may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. See "Business-Government Regulation-BLA Submission and Review".

In addition, the FDA or comparable foreign authorities may change the requirements for clinical development and approval, which may alter our clinical development plans and increase our costs. If the FDA does not believe we have sufficiently demonstrated that the selected doses for our product candidates maximize not only the efficacy of such candidate, but the safety and tolerability as well, our ability to progress our clinical trials and ultimately commercialize a product candidate may be delayed and our costs may be increased.

Any regulatory approvals that we may receive for our programs will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the program, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve our programs, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve our programs, our programs and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current cGMPs and GCPs for any clinical trials that we conduct following approval.

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated.

The Patient Protection and Affordable Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference

product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

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

We may not be able to meet requirements for the chemistry, manufacturing and control of our programs.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our CDMO partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation, manufacturing the drug product, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. Meeting these chemistry, manufacturing and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing and control requirements, we may not be successful in getting our products, including SL-325, approved.

Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including disruptions caused by government shutdowns, changes in leadership and/or policy at the FDA and/or the department of health and human services, reduced staffing in the federal government, and public health crises. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development of our most advanced product candidate, SL-325, or other product candidates, which could have a material adverse effect on our business.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our compounds on animals before initiating clinical trials involving humans. To the extent the activities of animal rights groups are successful, our research and development activities may be interrupted, delayed, or become more expensive.

Current and future laws and regulations may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. In August 2022 the IRA was enacted, which, among other provisions, included several measures intended to lower the cost of prescription drugs and enact related healthcare reforms. Since enactment of the IRA, the Centers for Medicare & Medicaid Services and other federal agencies have issued, and continue to issue, regulations and guidance to implement key provisions of the IRA, including provisions relating to Medicare drug price negotiation, inflation-based rebates, redesign of the Medicare Part D benefit and limits on patient out-of-pocket costs. Certain of these provisions are being implemented on a phased basis and are subject to ongoing rulemaking, interpretation and, in some cases, legal challenges. We cannot be sure whether additional legislation or rulemaking related to the IRA or other healthcare reforms will be issued or enacted, the manner in which the IRA will ultimately be implemented or interpreted, or what impact, if any, such developments may have on the pricing, reimbursement, commercial viability or profitability of any of our drug candidates, if approved for commercial use, in the future.

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers, and third-party payors are subject to applicable healthcare laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. See "Business-Government Regulation-Other Healthcare Laws and Compliance Requirements" for a more detailed description of the laws that may affect our ability to operate.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, as well as damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming, may require significant personnel resources, and may impair our business even if we are successful in defending against such claims. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our employees, independent contractors, principal investigators, contract research organizations ("CROs"), consultants, commercial partners, suppliers, and vendors acting for us or on our behalf may engage in misconduct or other improper activities, including noncompliance with applicable laws and regulations.

We have adopted a code of conduct, but it is not always possible to identify and deter such 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 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 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. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and 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, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We rely on third parties to supply raw materials and to manufacture our product candidates. The manufacture of our product candidates is complex and our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

The process of manufacturing our current and future product candidates is complex and highly regulated. We do not currently own or operate any cGMP manufacturing facilities, and we do not currently have any in-house cGMP manufacturing capabilities. Consequently, we expect to rely on third-party contract manufacturers to produce sufficient quantities of our current and future product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards. There can be no assurance that a manufacturer will be able to successfully produce satisfactory product on a timely basis. With legacy programs in the past, the manufacture of our product candidates by third-party manufacturers was, in the normal course of business, negatively impacted by 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. If we are unable to successfully and timely produce sufficient supply of our current and future product candidates, our planned clinical trials may be delayed and materially and adversely harm our business.

As part of our process development efforts, we also may make changes to our manufacturing processes at various points during development for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. We have invested in an in-house process development pilot plant to reduce our reliance on third parties for our process development efforts, however we cannot guarantee that these efforts will result in useful changes to our manufacturing processes. Any changes to our manufacturing processes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the

results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMPs and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, packing, storage, and distribution of the product, which are intended to ensure that biological products are safe and that they consistently meet applicable requirements and specifications. We are dependent on third parties for all of these activities, and we have limited ability to prevent or control the risk that such activities will not be in compliance with cGMP. In addition, the storage and distribution of our product candidates for use in clinical trials is subject to extensive regulation by the FDA and other regulatory authorities. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in our clinical trials and development efforts, or a delay in or failure to obtain regulatory approval of any of our product candidates.

Pharmaceutical manufacturers are also subject to extensive oversight by the FDA and comparable regulatory authorities in other jurisdictions, which include continual review and periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer's facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a "Form FDA 483" report. If observations in the Form FDA 483 report are not addressed in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter or proceed directly to other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in further enforcement action that could lead to a shortage of products and harm our business. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Moreover, if the FDA determines that our third-party manufacturers are not in compliance with applicable laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries.

We rely, and expect to continue to rely, on third parties to conduct preclinical studies, nonclinical studies, and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory authorizations or approvals required to develop or commercialize our product candidates and our business could be materially and adversely affected.

We have relied, and plan to continue to rely, upon third parties, including independent clinical investigators and third-party CROs, to help establish and conduct certain preclinical studies, nonclinical studies, and clinical trials and to monitor, record, and manage data for our ongoing preclinical and nonclinical programs and current and future clinical programs. We currently and in the future expect to rely on these parties for execution of certain preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing, and completion of these preclinical studies, nonclinical studies, and clinical trials and the management of data developed through these preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. If we or any of these third parties fail to comply with applicable good laboratory practice, or good clinical practice regulations, such data may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or nonclinical studies, or clinical trials before approving our marketing applications. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

There is a limited number of third-party service providers that specialize in or have the expertise required to achieve our business objectives. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or to do so in a timely manner or on commercially reasonable terms. If the third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines; if they need to be replaced; or if the quality or accuracy of the preclinical, nonclinical, or clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements, or for other reasons, our preclinical studies, nonclinical studies, or clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We may not realize the benefits of any future collaboration or licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects, and results of operations may be materially and adversely affected.

We have in the past entered into, and may decide in the future to enter into, collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of our product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction. We may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs. We also may not be able to ensure that any future collaboration partners adequately protect and do not misuse our intellectual property. We and our future collaboration partners may disagree regarding the research plan or the development plan for product candidates on which we are collaborating and disputes could arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources. If our strategic collaborations do not result in the successful development and commercialization of product candidates or if one of our collaborators fails to act under the collaboration agreement or terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. In addition, if a collaboration is terminated, it may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, we were party to collaboration agreements with Takeda Pharmaceutical Company, Ltd. ("Takeda")and Ono Pharmaceutical Company, Ltd. ("Ono"), which were terminated, and will not receive any future funding under those agreements. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate such products or business into our existing operations and company culture.

If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other supply difficulties, our business may be materially and adversely affected.

We work closely with our suppliers to ensure the continuity of supply of raw and intermediate materials but cannot guarantee these efforts will always be successful. We have experienced, and may continue to experience in the future, raw and intermediate materials supply shortages, which has contributed to manufacturing delays and impacted the progress of our clinical trials. Further, while we work to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier, and there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner and could delay completion of our early-stage clinical trials, product testing, and potential regulatory approval of our product candidates.

Risks Related to Intellectual Property and Information Technology

Our success depends upon our ability to obtain and maintain patents and other intellectual property rights to protect our technology, including SL-325, methods used to manufacture our product candidates, formulations thereof, and the methods for treating patients using those product candidates.

The prosecution, enforcement, defense, and maintenance of intellectual property rights are often challenging, costly, and uncertain. Contributors to these challenges and uncertainty include the early stage of our products and our intellectual property portfolio development; the unpredictability of what patent claim scope will ultimately be issued to protect our products and how the law will change or develop as to scope, length, and enforcement of patent protection; the competitive and crowded inflammatory and autoimmune space; complicated and unforgiving procedural, documentary, and fee requirements of the U.S. PTO, and foreign patent offices; lack of perfect visibility into what our competitors are doing and the patent claim scope they are obtaining; lack of perfect ability to determine what prior art may exist; and the expense and time consuming nature of patent portfolio development across relevant jurisdictions. For at least these reasons, the issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. We cannot be sure that patent coverage will issue, or will be maintained, to protect our products in some or all relevant jurisdictions. We cannot be sure that we will not encounter freedom-to-operate challenges in the development and commercialization of our product candidates. We cannot be sure our trademarks and trade names are sufficient to build name recognition in our markets of interest. We cannot be sure our measures to protect our trade secrets will be sufficient. Failure to protect or enforce these rights adequately could harm our ability to develop and market our product candidates and could impair our business.

Others may challenge our patents or other intellectual property as invalid or unenforceable.

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. 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if patents do successfully issue and even if such patents cover our product candidates and extend for a commercially-relevant time, third parties may initiate invalidity, non-infringement, opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation actions in court, before patent offices, or similar proceedings challenging the validity, inventorship, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, held unenforceable, or circumvented. Such challenges and potential negative results could materially and adversely affect our business.

Furthermore, even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention, such as 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. Additionally, some countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties; and some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Additionally, our competitors or other third parties may be able to evade our patent rights by developing new fusion proteins, antibodies, biosimilar antibodies, or alternative technologies or products in a non-infringing manner. These risks may impact our ability to enjoy the protection we obtain, and may materially and adversely impact our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our product candidates without infringing or otherwise violating the intellectual property and other proprietary rights of third parties.

Others may accuse us of infringing their intellectual property. Contested proceedings are lengthy, time consuming, and costly, and we cannot guarantee that our operations and activities do not, or will not in the future, infringe existing or future patents. We also 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 product candidates or necessary for the commercialization of our product candidates in any jurisdiction. Furthermore, we may be subject to third-party claims asserting that our employees, consultants, contractors, collaborators, or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property. These and related risks to defending against third-party claims may materially and adversely affect our business.

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. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. As such, there may be applications of third parties now pending or recently revived patents of which we are unaware.

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 product candidates. We may incorrectly determine that our product candidates 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. We cannot provide any assurances that third-party patents do not exist that might be enforced against our current technology, including our platform technologies, product candidates and their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture, 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.

We rely, in part, on in-licensed patents and other intellectual property rights to develop and commercialize our product candidates. We may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our product candidates or other attributes of our product candidates, or our compounds, including SL-325. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, which can be expensive and time-consuming, or we may have to enter into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all.

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. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. The target of our product candidates has also been the subject of research by many companies that have filed patent applications or have patents related to such target and therapeutics methods related to that target.

Disputes may arise with our licensors of patents and other intellectual property rights. We may yet need to obtain licenses from others for continued development and commercialization of our product candidates, and we may be unable to secure those licenses on commercially reasonable terms or at all. 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, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain, or use these proprietary rights. 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.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer. All licenses impose obligations upon us that must be met to maintain the license. If we are unable to meet these obligations, we may be required to pay damages and our licensors may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we and/or our licensors must cooperate in order to enforce such patents against third parties, and such cooperation may not be provided. We also may rely on our licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property rights we license from them and may have limited control over these activities or any other intellectual property rights that may be related to our in-licensed intellectual property rights.

In addition, our competitors may independently develop substantially equivalent trade secrets, proprietary information, or know-how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances, and to make it more likely that we have our freedom to operate, we may also decide to publish some know-how to make it difficult for others to obtain patent rights covering such know-how, at the risk of potentially exposing our trade secrets to our competitors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may depend on intellectual property licensed from third parties and if we fail to comply with our obligations under any license or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot determine currently the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

We may enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents throughout the world, as appropriate, the process of obtaining patents is time-consuming, expensive, and sometimes unpredictable in other countries. In addition, differences in patent laws throughout the world may make it difficult to obtain uniform patent coverage in the jurisdictions where we have patent protection. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all markets.

We have not, and will not, file for patent protection in all national and regional jurisdictions where such protection may be available. Filing, prosecuting, and defending patents on all of our research programs, compounds, and product candidates in all countries throughout the world would be prohibitively expensive, and, therefore, the scope and strength of our intellectual property rights will vary from jurisdiction to jurisdiction.

Changes in patent laws in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in foreign jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The patent laws of the U.S. and foreign jurisdictions, as well as the rules of the U.S. PTO and foreign patent offices, change from time to time. Further changes to the patent laws and/or rules of the U.S. PTO and foreign patent offices may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. The Supreme Court and other federal courts also regularly rule on patent cases, including those involving the life sciences. Those decisions can change the interpretation of patent laws; for example, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. These changes to patent laws and subsequent court decisions related to patent rights have created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts and the U.S. PTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make product candidates similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have a material and adverse effect on our business;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future strategic partners 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, misappropriating, or otherwise violating our intellectual property rights;
- our pending patent applications might not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we cannot predict the degree and range of protection any issued patents will afford us against competitors, whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications, or whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose;
- 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;

- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

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

We 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.

Trade secrets and/or proprietary know-how can be difficult to protect or maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, we generally require our employees, consultants, contractors, collaborators, advisors, and other third parties to enter into confidentiality agreements with us. Despite these efforts, any of these parties may unintentionally or willfully breach the agreements and disclose our confidential information, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. 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. Enforcing a claim that a third party illegally obtained and is using trade secrets and/or confidential know-how is also expensive, time-consuming, and unpredictable.

The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the United States are less willing or are unwilling to protect trade secrets or other proprietary information.

Any sort of contested proceeding related to intellectual property, whether offensive or defensive, may cause us to incur significant expenses and would be likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities, and may impact our reputation.

There could be public announcements of the results of or developments in hearings, motions or other interim proceedings and if securities analysts or investors perceive these results or developments to be negative, it could have a material and adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development 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. Infringement or related suits against us by others could result in damages awards against us or injunction or other equitable relief precluding continued commercialization of our products. 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.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and in order to maintain the patent once issued. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents within prescribed time limits. If we fail to maintain the patents and patent applications covering our product candidates or if we otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would have a material and adverse effect on our business.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could materially and adversely affect our business.

In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information in digital form. Despite the implementation of security measures, our information technology systems and data, and those of our current or future CROs or other contractors and consultants, are vulnerable to compromise or damage from computer hacking,

malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Although, to our knowledge, we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations or subject us to litigation or regulatory actions taken by governmental authorities. See the sections titled "Business-Government Regulation-Data Privacy and Security" and "Cybersecurity." Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price, stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

In addition, because we collect, store and transmit confidential information in digital form, we, and third parties who we work with, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations. See the section titled "Business-Government Regulation-Data Privacy and Security" for a more detailed description of the laws that may affect our ability to operate.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

The market price of our common stock may be highly volatile and may fluctuate significantly as a result of a variety of factors, some of which are related in complex ways and many of which are beyond our control, including the factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. In addition, the stock market in general, and The Nasdaq Stock Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. We have in the past been subject to securities class action litigation following periods of volatility in the market price of our securities. While this litigation was settled, if any similar litigation was instituted in the future, it could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. See the discussion of Legal Proceedings in Part I, Item 3 of this Form 10-K.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares sold through our ATM Facility or shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

General Risk Factors

Our business could be adversely affected by economic downturns, inflation, fluctuating interest rates, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, natural disasters, public health crises, such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced heightened volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, slower or uneven economic growth, supply chain shortages, fluctuating interest and inflation rates, changes in trade policies, including tariffs or other trade restrictions or the threat of such action, and uncertainty about economic stability. Recent and ongoing inflationary pressures, elevated interest rates, tightening monetary policies and volatility in global capital markets have increased uncertainty and may persist or recur. For example, fluctuating interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending, investor risk tolerance and access to capital, and ongoing military conflicts throughout the world have contributed to volatility in global capital markets and may have further global economic consequences, including disruptions of the global supply chain and international trade. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. The FDIC may not make all account holders whole in the event of bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock depends in part upon research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. As we have experienced in the past, if any analyst who may cover us in the future were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline. In addition, the price of our common stock could decline if one or more analysts downgrade our stock or issue inaccurate or other unfavorable commentary or research.

The requirements of being a public company may strain our resources, result in litigation, and divert management's attention.

As a public company, we are subject to certain reporting requirements, listing requirements, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could

materially and adversely affect our business and operating results. As of January 1, 2026, we no longer qualify as an "emerging growth company" and will consequently have increased reporting obligations beginning with this Annual Report on Form 10-K. Any additional change in our filer status could trigger a requirement to begin complying with Section 404(b) of the Sarbanes-Oxley Act of 2002, and our independent registered public accounting firm would have to evaluate and report on the effectiveness of internal control over financial reporting, increasing our costs. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

By disclosing information in this and in future filings required of a public company, our business and financial condition will become more visible, which has resulted in, and may in the future result in, threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

Litigation filed against us could harm our business, and insurance coverage may not be sufficient to cover all related costs and damages.

We face the threat of legal claims and regulatory matters involving various aspects of our business. Given the volatility of the trading price of our common stock, and the prevalence of shareholder litigation generally, we face a risk of lawsuits alleging violations of the securities laws. Litigation is inherently uncertain, and adverse rulings may occur, including awards of monetary damages, that may have a material adverse impact on our business. These lawsuits may also divert management's attention and resources, and may require us to incur substantial costs, some of which will not be covered by insurance.

We may become exposed to costly and damaging liability claims, either when testing a product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of a product candidates in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although we currently maintain adequate product liability insurance for our product candidates, it is possible that any liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to report upon the effectiveness of our internal control over financial reporting. To comply with the requirements of being a reporting company under the Exchange Act, we have implemented and will continue to implement additional financial and management controls, reporting systems, and procedures and we have hired and will continue to hire additional accounting and finance staff. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future.

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 have 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 a required related party transaction disclosure. 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.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws each contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of the Company or changes in our management that the stockholders of the Company may deem advantageous. As a Delaware corporation, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of the Company.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction) is the exclusive forum for certain actions. It also provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits. In addition, there is uncertainty as to whether a court would enforce such provisions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially and adversely affect our business.

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

As of December 31, 2025, we had U.S. federal and state net operating loss ("NOL"), carryforwards of $251.0 million, which may be available to offset future taxable income. As of December 31, 2025, we also had gross federal tax credits of $23.0 million, which may be used to offset future tax liabilities. Our capital loss and tax credit carryforwards as of December 31, 2024 began to expire in 2025. Use of our NOL carryforwards and tax credit carryforwards depends on many factors, including having current or future taxable income, which cannot be assured.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

In the ordinary course of our business, we collect, use, store, and transmit digitally large amounts of confidential, sensitive, proprietary, personal, and health-related information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to help assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by dedicated information technology resources, including both company and consultant personnel, and led by our Chief Business Officer. The processes include mechanisms, controls, technologies, systems, and other processes designed to help prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and help maintain a stable information technology environment. For example, we conduct penetration and vulnerability testing, data recovery testing, security audits, and ongoing risk assessments of our IT environment. We also conduct technology due diligence on and audits of our key vendors, CROs, and other contractors and suppliers supporting our clinical trials. We also conduct regular employee trainings on cyber and information security. In addition, we consult with experienced outside advisors and experts on a regular basis to assist with assessing, identifying, and managing cybersecurity risks.

Our Chief Business Officer, who reports directly to the Chief Executive Officer, together with certain members of our senior leadership team, are responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework evaluated at least quarterly. Since the beginning of the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if

realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors," under the heading "Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could materially and adversely affect our business."

The Board of Directors, as whole and at the committee level, has oversight for the most significant risks facing us and on our processes to help identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, reviews cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Chief Business Officer.

Item 2. Properties

Our corporate headquarters are located in Austin, Texas where we currently occupy approximately 5,400 square feet of office space under a lease that expires on December 31, 2029. We use this facility for administrative purposes.

We currently lease approximately 32,200 square feet of office and laboratory space in Durham, North Carolina under a lease that expires on December 31, 2028. We use this facility for research and development purposes.

We believe these spaces to be sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business. We are not presently a party to any material legal proceedings, and we are not currently aware of any pending or threatened legal proceeding against us that, in the opinion of our management and if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows.

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

Our common stock is traded on The Nasdaq Global Select Market under the symbol "STTK". At March 5, 2026, there were approximately 24 stockholders of record of our common stock. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have never paid dividends on our common stock and do not anticipate that we will do so in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

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 our financial statements and related notes appearing in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." You should carefully read the "Cautionary Note About Forward-Looking Statements" and "Risk Factors" sections of this Annual Report on Form 10-K to gain an understanding of the important factors that could cause actual results to differ materially from the results described below.

Overview

We are a clinical-stage biotechnology company pioneering the development of potentially first-in-class monoclonal and bispecific Death Receptor 3 ("DR3") blocking antibodies for the treatment of patients with inflammatory and immune-mediated diseases. Our expertise in protein engineering and the development of novel tumor necrosis factor ("TNF") receptor therapeutics come together in our lead program, SL-325, a potentially first-in-class DR3 blocking antibody designed to achieve a more complete blockade of the clinically validated DR3/TL1A pathway than TL1A blocking antibodies.

SL-325 is a high-affinity DR3 blocking monoclonal antibody. DR3 is the sole known receptor for tumor necrosis factor like ligand 1A ("TL1A"). In our head-to-head preclinical studies, SL-325 blocked TL1A binding to DR3 better than sequence equivalents of leading TL1A blocking antibodies. We believe that the underlying biological differences in the expression of DR3 and TL1A, and the design characteristics of SL-325, may allow SL-325 to achieve best-in-class clinical remission rates in patients with IBD due to a more complete and durable blockade of the clinically validated DR3/TL1A pathway. Additionally, we expect that SL-325 has the potential to demonstrate a superior immunogenicity profile in comparison to TL1A blocking antibodies. By targeting DR3 instead of TL1A, we expect to avoid the formation of immune complexes, which we believe are the primary source of immunogenicity for all TL1A blocking antibodies, and lead to high rates of anti-drug antibody ("ADA") formation toward TL1A targeting antibodies. ADA to TL1A targeting antibodies has been shown to reduce efficacy in IBD patients. We are currently conducting a single ascending dose ("SAD") and multiple ascending dose ("MAD") Phase 1 clinical trial evaluating SL-325 in healthy volunteers. We expect this Phase 1 clinical trial to be completed in the second quarter of 2026. We expect to initiate a randomized, placebo-controlled Phase 2 clinical trial evaluating SL-325 in patients with Crohn's Disease ("CD") in the third quarter of 2026.

TL1A is the sole known signaling ligand for DR3, and TL1A does not signal through any other receptors. Thus, we believe that the clinical safety profile of TL1A blocking antibodies generated to date in clinical trials conducted by other parties derisks the clinical safety profile for DR3 blockade. The lack of toxicity of SL-325 in our recently completed non-human primate ("NHP") acute toxicology study also suggests a potentially favorable clinical safety profile. We engineered SL-325 to lack any Fc gamma receptor binding function, and SL-325 has not shown any evidence in our preclinical studies to date of antibody dependent cellular cytotoxicity or cellular phagocytosis, which further supports a potentially derisked safety profile. We have demonstrated that SL-325 binds an epitope on DR3 that does not trigger receptor-mediated endocytosis, and the binding of SL-325 to DR3 was shown to be highly durable in our preclinical assays and in our NHP studies. Because DR3 is expressed on circulating, peripheral blood lymphocytes, we are able to directly measure DR3 receptor occupancy ("RO"), and

our nonclinical studies suggest that blockade is durable for at least two months as a result of the properties of SL-325 and the stable expression of DR3. In our preclinical studies, including our acute NHP toxicology study, the RO and pharmacokinetic ("PK") profile of SL-325 suggest extended dosing intervals, which are being further characterized in our ongoing Phase 1 clinical trial.

DR3 has a distinct expression pattern from TL1A, and, consequently, blocking the receptor may allow a more complete and durable blockade of the axis, which we believe will translate to improved efficacy in patients with IBD. DR3 and TL1A have distinct expression patterns within the gastrointestinal tract ("GI") of patients with IBD, including both ulcerative colitis ("UC") and Crohn's disease ("CD"). The cells within the GI tract that are capable of expressing TL1A include tissue resident antigen presenting cells and other non-hematopoietic cells. While TL1A is not usually expressed, when antigen presenting cells are exposed to inflammatory signals, a wave of TL1A mRNA expression begins, which peaks within 12 hours and ceases within 24 hours. In contrast, DR3 is stably expressed, primarily by lymphocytes both in the peripheral blood and in tissues. Direct comparison of TL1A and DR3 expression in the GI tracts of patients with IBD shows that TL1A is only upregulated in the actively inflamed areas of the GI tract. In contrast, DR3 is more abundant than TL1A and is upregulated in both actively inflamed parts of the GI tissue and in the adjacent non-inflamed tissue. The absence of TL1A in the non-inflamed areas of the bowel eliminates the mechanism through which TL1A blocking antibodies would be retained in non-inflamed areas of the GI tract. Because inflammation observed in UC and CD can wax and wane in different areas of the bowel over time, stable blockade of DR3 may reduce the spread of inflammation and may contribute to higher rates of clinical and endoscopic remission than what TL1A blocking antibodies have achieved to date.

A source of immunogenicity shared by all TL1A blocking antibodies is the formation of immune complexes between soluble TL1A in the blood and the anti-TL1A antibodies. Binding of soluble TL1A in the blood by anti-TL1A antibodies leads to a significant increase in the concentration of total TL1A in the blood. These immune complexes have contributed to ADA formation in more than 64% of subjects treated with afimkibart, tulisokibart, or duvakitug in third-party clinical trials. A third-party Phase 2 trial testing the efficacy of afimkibart in CD patients demonstrated that ADA caused accelerated clearance of afimkibart, which reduced efficacy in an ADA titer dependent manner. Because DR3 is a membrane-restricted receptor, and SL-325 was engineered to bind an epitope on DR3 that is not found on DcR3, immune complex formation is not expected with SL-325. Data generated from our GLP acute NHP toxicology study, along with *in silico* assessment of immunogenicity risk, consistently suggest that SL-325 may have single digit ADA rates in humans. Thus, we expect that SL-325 has the potential to demonstrate a best-in-mechanism immunogenicity profile, and we expect that this superior immunogenicity profile alone will lead to improved efficacy as a monotherapy, at both the induction and maintenance time points.

Additionally, there is a high degree of sequence identity between certain third-party anti-TL1A antibodies, including tulisokibart, afimkibart, and duvakitug, and potential third-party combination agents, including vedolizumab, risankizumab, mirikizumab, and guselkumab. This overlap in sequence identity introduces a risk that ADAs generated against TL1A antibodies may cross-bind to these potential combination agents and could cause accelerated clearance of both the anti-TL1A antibody and other antibodies included in a coformulation, and that this may impact the efficacy of each agent. Because of this, we believe that SL-325 may allow for improved efficacy in combination with other agents, compared to TL1A targeting antibodies.

We are planning initial clinical development of SL-325 in patients with CD. The clinical success of several TL1A blocking antibodies to date suggests that SL-325 may have monotherapy disease modifying activity early in clinical development. As described above, we believe that targeting DR3 may be more efficacious than targeting TL1A in patients with IBD. We expect to complete enrollment in the ongoing Phase 1 clinical trial for SL-325 in healthy volunteers in the second quarter of 2026, and initiate our Phase 2 clinical trial in patients with CD in the third quarter of 2026.

We also plan to evaluate SL-325 in other inflammatory and immune-mediated diseases where the DR3/TL1A axis is implicated.

In addition to SL-325 and SL-425 (a half-life extended version of SL-325), we are developing bispecific antibodies which co-target DR3 and other clinically validated targets in immune mediated and inflammatory diseases. Inhibition of the TL1A/DR3 axis may be mechanistically distinct from the IL-23/IL-23R, IL-17/IL-17R, TSLP/TSLP-R or α4β7/MADCAM-1 axes (as examples). Thus, dual inhibition of the TL1A/DR3 axis with coformulated or bispecific antibodies may provide additive clinical benefit in a variety of immune mediated and inflammatory diseases. As seen with TL1A directed antibodies, two third-party TL1A-directed bispecific antibodies, AMG966 and RO7837195, have also demonstrated nearly 100% ADA formation following a single dose in Phase 1 clinical trials. The mechanism of ADA formation was reported to be secondary to large immune complex formation for AMG966, which we believe is also true for RO7837195. The emerging clinical data from TL1A-directed bispecific antibodies is similar to the prior failure of TNFα-directed bispecific antibodies, which we believe is because both TNFα and TL1A are soluble trimeric proteins found in the blood, and cause immunogenicity secondary to large immune complex formation. We expect that our DR3-directed bispecific antibodies to be less immunogenic than TL1A-directed bispecifics. DR3 may thus provide a differentiated target in a bispecific antibody format, providing advantages over

TL1A-directed bispecific antibodies. Additionally, development of bispecific antibodies may enable more efficient clinical development than is expected for multi-antibody coformulations, and may avoid some of the challenges associated with potential immunogenicity in certain coformulations, as described above.

For the years ended December 31, 2025 and 2024, our net loss was $48.8 million and $75.4 million, respectively. We have not been profitable since inception, and as of December 31, 2025, we had an accumulated deficit of $430.5 million and $78.1 million in cash and cash equivalents and short-term investments. We expect to continue to incur significant expenses and operating losses in the near term in connection with our ongoing activities, as we:

- continue Phase 1 clinical development of our lead product candidate, SL-325;
- initiate nonclinical studies and clinical trials for additional product candidates that we may identify in the future, including potential DR3 based bispecific antibodies targeting DR3 together with another biologically relevant target;
- manufacture sufficient quantities of bulk drug substance and drug product to support our ongoing and planned nonclinical studies and clinical trials;
- maintain our operational, financial, and management systems;
- retain key personnel and infrastructure to support our nonclinical development, research and manufacturing, and future clinical development efforts;
- utilize our in-house process development and manufacturing capabilities;
- continue to develop, perfect, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company and expenses incurred in connection with ongoing and future litigation, if any.

We do not expect to generate significant product revenue unless and until we successfully complete development and obtain regulatory and marketing approval of, and begin to sell, one or more of our product candidates, if ever, which we expect will take several years. We expect to spend a significant amount in development and marketing costs prior to such time. We may never succeed in achieving regulatory and marketing approval for our product candidates. We may obtain unexpected results from our nonclinical studies and clinical trials. We may elect to discontinue, delay, or modify nonclinical studies and clinical trials of our product candidates. We may be adversely affected by inflationary pressures and the macroeconomic environment, which are beyond our control. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time as we can generate significant product revenue, if ever, we expect to continue to seek private or public equity and debt financing, and/or additional collaborations with third parties, to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our product candidates. In addition, we may not be profitable even if we commercialize any of our product candidates.

Global Economic Considerations

The global macroeconomic environment is uncertain, and could be negatively affected by, among other things, inflation, slower growth or recession, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, instability or volatility in the global capital and credit markets, supply chain weaknesses, financial institution instability, changes to fiscal and monetary policy or government budget dynamics and instability in the geopolitical environment. Such challenges have caused, and may continue to cause, recession fears, high interest rates, foreign exchange volatility, and inflationary pressures. At this time, we are unable to quantify the potential effects of this economic instability on our future operations.

Components of our Results of Operations

We have no products approved for commercial sale, and we have not generated any revenue from commercial product sales.

Related Party License Revenue

Revenue recognized in 2025 was a result of an exclusive license agreement (the "Kayak Agreement") with Kayak Therapeutics, Inc. (“Kayak”) for our oncology-focused TRIM7 program, which we entered into in August 2026. Pursuant to the Kayak Agreement, we received preferred stock of Kayak with a fair market value of $1.0 million as upfront consideration for entering into the agreement and recognized the consideration as license revenue.

Collaboration Revenue

Revenue recognized in 2024 was a result of collaboration agreements with Ono Pharmaceutical Co., Ltd ("Ono") and ImmunoGen, Inc. (“ImmunoGen”).

In February 2024, we entered into a collaboration and license agreement with Ono (the "Ono Agreement") pursuant to which we and Ono collaborated in the research and preclinical development of certain compounds selected by Ono from our pipeline of bifunctional fusion proteins directed toward a pair of prespecified targets for potential treatment of autoimmune and inflammatory diseases. We have completed all obligations under the agreement and have accordingly recognized $5.4 million in revenue pursuant to terms of the Ono Agreement including the $2.0 million paid for the option to enter into an exclusive license with us. On September 30, 2024, we and Ono mutually agreed to terminate the Ono Agreement and the related option pursuant to the terms of the agreement.

As of December 31, 2024, we completed our obligations under the collaboration agreement with ImmunoGen, and have recognized all revenue pursuant to the terms of that agreement.

Operating Expense

Research and Development Expense

Our research and development expenses consist primarily of costs incurred in connection with the discovery and development of our current and potential future product candidates. These expenses include:

- expenses incurred to conduct our clinical trials, including expenses associated with clinical trials of SL-325 and any potential product candidates we may advance in the future, as well as the expenses associated with prior clinical trials of SL-172154 and the associated wind-down activities;
- costs of manufacturing nonclinical study and clinical trial materials, including the costs of raw materials required for manufacturing;
- process development activities to optimize manufacturing processes, including the development and validation of Phase 3 and commercial manufacturing processes and analytical methods;
- expenses incurred to conduct our nonclinical studies;
- employee-related expenses, including salaries, benefits, and stock-based compensation;
- laboratory materials and supplies used to support our research activities;
- fees paid to third parties who assist with research and development activities;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility-related costs.

The following table summarizes our research and development expenses by product candidate:

(in thousands)	Year ended December 31, 2025	2024
SL-325 [1]	$ 10,777	$ 4,574
SL-172154	2,637	27,608
Other pipeline compounds	3,289	9,923
Internal costs, including personnel related benefits, facilities, and depreciation	18,570	25,106
Total research and development costs	$ 35,273	$ 67,211

[1] Expenses for SL-325 that were incurred prior to its nomination as product candidate are included in “other pipeline compounds” in the table above.

Research and development activities are central to our business model. We are focused on the preclinical and clinical development of SL-325 and other DR3 targeted assets, and conducting additional research on other potential product candidates. Product candidates in earlier stages of development generally have lower development costs than those in later stages of development. In 2026, we anticipate initiating Phase 2 clinical trial(s) for SL-325. Accordingly, we expect an increase in research and development and expense year-over-year, as we incur incremental clinical trial expense and additional costs

associated with commensurate increases in our workforce to support these efforts. In October 2024, we discontinued clinical development of SL-172154.

The process of conducting the necessary nonclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including:

- the safety and efficacy of our product candidates;
- nonclinical data for our product candidates;
- investment in our pipeline;
- competition;
- manufacturing capability; and
- commercial viability.

We may never succeed in achieving regulatory approval for any of our product candidates due to the uncertainties discussed above. We are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if ever.

General and Administrative Expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits, and stock-based compensation expense, for employees and consultants in executive, finance, accounting, legal, information technology, business development, and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation, and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property, corporate, and litigation matters and fees for accounting and tax services.

If any of our current or future product candidates, including SL-325, continues to advance through clinical development, or obtains regulatory approval, we expect that we would incur increased expenses associated with building the appropriate general and administrative support for our increased research and development activities, or building a sales and marketing team.

Other Income

Other income consists of interest earned on our cash, cash equivalents and short-term investments, which consists of amounts held in a money market fund and government obligations as well as investment fees and realized gain or losses on short-term investments (if any).

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net operating losses ("NOLs") we have incurred or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized. Our capital loss and tax credit carryforwards as of December 31, 2024 began to expire in 2025.. We have recorded a full valuation allowance against our deferred tax assets at each balance sheet date.

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	Year Ended December 31, 2024	Change Dollar	Change Percentage
Related party license revenue	$ 1,000	$ —	$ 1,000	100.0 %
Collaboration revenue	—	5,721	(5,721)	(100.0)%
Total revenue	1,000	5,721	(4,721)	(472.1)%
Operating expenses:				
Research and development	35,273	67,211	(31,938)	(47.5)%
General and administrative	17,235	19,077	(1,842)	(9.7)%
Loss from operations	(51,508)	(80,567)	29,059	(36.1)%
Other income	2,699	5,157	(2,458)	(47.7)%
Net loss	$ (48,809)	$ (75,410)	$ 26,601	(35.3)%

Related Party License Revenue

Related party license revenue increased by $1.0 million, or 100.0%, for the year ended December 31, 2025 from $0.0 million for the year ended December 31, 2024. The increase in related party license revenue was a result of license revenue recognized pursuant to the Kayak Agreement of $1.0 million.

Collaboration Revenue

Collaboration revenue decreased by $5.7 million, or 100.0%,for the year ended December 31, 2025 from $5.7 million for the year ended December 31, 2024. The decrease in collaboration revenue was a result of completing all obligations and recognizing all revenues associated with the Ono and ImmunoGen collaboration agreements in 2024.

Research and Development Expense

Research and development expense decreased by $31.9 million, or 47.5%, to $35.3 million for the year ended December 31, 2025 from $67.2 million for the year ended December 31, 2024. The decrease in research and development expense was primarily due to a decrease of $31.5 million as a result of the discontinuation of the SL-172154 program and related workforce reductions and a decrease of $6.6 million in other pipeline compounds cost, partially offset by an increase of $6.2 million in SL-325 expenses primarily as a result of moving SL-325 into clinical development in 2025.

General and Administrative Expense

General and administrative expenses decreased by $1.8 million, or 9.7%, to $17.2 million for the year ended December 31, 2025 from $19.1 million for the year ended December 31, 2024. The decrease is primarily the result of a $1.2 million decrease in compensation and related benefit expenses as a result of workforce reductions in 2024 as well as a decrease of $0.6 million in legal fees.

Liquidity and Capital Resources

Since our inception, our primary sources of liquidity have been generated by sales of our common stock, pre-funded warrants, common stock warrants, convertible preferred stock, and convertible notes, and through collaboration agreements. As of December 31, 2025, we had an accumulated deficit of $430.5 million and $78.1 million of cash and cash equivalents and short-term investments.

In August 2025, we issued and sold 15,225,158 shares of common stock, pre-funded warrants to purchase up to 37,410,188 shares of common stock, and accompanying common stock warrants to purchase up to 52,635,346 shares of common stock for gross proceeds of $45.7 million. In January 2026, 4,866,055 common stock warrants were exercised for gross proceeds of $5.3 million and we may receive an additional $51.7 million in gross proceeds if the remaining common stock warrants are exercised.

In January 2026, we entered into a sales agreement (the “Sales Agreement”) with Leerink Partners LLC (the “Sales Agent”), pursuant to which we may offer and sell up to $75.0 million of shares of our common stock from time to time through our ATM Facility. The Sales Agent is generally entitled to compensation at a commission equal to up to 3.0% of the aggregate

gross sales price per share sold under the Sales Agreement. We sold 5,000,000 shares of common stock at $4.28 per share for gross proceeds of $21.4 million in January 2026.

Capital Resources and Funding Requirements

Our primary uses of cash, cash equivalents and short-term investments are to fund our operations, which consist primarily of research and development expenditures related to our programs, product development costs, research expenses, administrative support, capital expenditures related to bringing in-house certain process development and manufacturing capabilities, and working capital requirements. We anticipate incurring additional net losses and negative cash flows from operations in the near future until such time, if ever, that we can generate significant sales of our product candidates currently in development. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress and results of discovery, nonclinical development, laboratory testing, and clinical trials for our product candidates;
- the costs of process development and scale up of a commercially ready manufacturing process to support registrational clinical trials;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending other intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing, distribution and storage capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

Until we obtain regulatory approval to market our product candidates, if ever, we cannot generate revenues from sales of our products. Even if we are able to sell our products, we may not generate a sufficient amount of product revenues to finance our cash requirements. Accordingly, it will be necessary for us to seek to raise additional capital through equity offerings and/or debt financings or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of our development programs or patent portfolios. There can be no assurance that such funding may be available to us on acceptable terms, or at all. The issuance of equity securities may result in dilution to stockholders and the issuance of debt securities may have rights, preferences and privileges senior to those of our common stock and the terms of any such debt securities could impose significant restrictions on our operations. The failure to raise funds as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. Additionally, if additional funding is not secured when required, we may need to delay or curtail our operations until such funding is received, which would have a material and adverse impact on our business prospects and results of operations.

We believe that our cash, cash equivalents and short-term investments as of December 31, 2025 and the potential future proceeds assuming the full exercise of all outstanding common stock warrants will be sufficient to fund projected operations into 2029.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Year ended December 31,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (39,882)	$ (60,515)
Net cash used in investing activities	(7,887)	(8,511)
Net cash provided by financing activities	44,574	787
Decrease in cash and cash equivalents	$ (3,195)	$ (68,239)

Net Cash Used in Operating Activities

During the year ended December 31, 2025, net cash used in operating activities was $39.9 million and primarily reflected our net loss of $48.8 million, partially offset by noncash charges of $9.7 million and a net change in our operating assets and liabilities of $0.8 million. We expect to continue to use cash in our operating activities as we conduct our clinical trials and nonclinical studies, incur costs of manufacturing clinical trial and nonclinical study materials and continue process development activities to optimize our manufacturing processes.

During the year ended December 31, 2024, net cash used in operating activities was $60.5 million and primarily reflected by our net loss of $75.4 million, partially offset by noncash charges of $11.9 million and a net change in our operating assets and liabilities of $3.0 million.

Net Cash Provided by Investing Activities

During the year ended December 31, 2025, net cash used in investing activities was $7.9 million due primarily to purchases of government securities, net of sales and maturities of investments.

During the year ended December 31, 2024, net cash used in investing activities was $8.5 million due primarily to purchases of government securities, net of sales and maturities of investments.

Net Cash Provided by Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $44.6 million due to the sale of common stock, pre-funded warrants and common stock warrants, the exercise of stock options and common stock warrants and purchases pursuant to our employee stock purchase plan.

During the year ended December 31, 2024, net cash provided by financing activities was $0.8 million due to the exercise of stock options and purchases pursuant to our employee stock purchase plan.

Contractual Obligations and Other Commitments

See Note 6 and Note 7 to our financial statements found elsewhere in this Annual Report on Form 10-K for additional disclosures.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, the accrual for research and development expenses, and the valuation of stock-based awards. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our financial statements. We believe that the assumptions and estimates associated with our most critical accounting policies are those relating to revenue, accrued research and development costs and stock-based compensation.

Revenue Recognition

We have and may continue to enter into license and collaboration agreements with other companies. Arrangements with other companies may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering and patent committees. We evaluate the promised goods or services in the contract to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, we consider the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, we develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines, and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

Upon the amendment of an existing agreement, we evaluate whether the amendment represents a modification to an existing contract that would be recorded through a cumulative catch-up to revenue, prospective modification, or a separate

contract. If it is determined that it is a separate contract, we will evaluate the necessary revenue recognition through the five-step process described below.

When we conclude that a contract should be accounted for as a combined performance obligation and recognized over time, we then determine the period over which revenue should be recognized and the method by which to measure revenue. We generally recognize revenue using a cost-based input method.

We recognize collaboration revenue in an amount that reflects the consideration that we expect to receive in exchange for those goods or services when our customer or collaborator obtains control of promised goods or services. To determine revenue recognition for such arrangements, we perform the following five steps:

i. identify the contract(s) 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 within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

At contract inception, we assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the arrangement may consist of a license of, or options to license, our intellectual property and research, development and manufacturing services. We may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) are separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

We determine transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, we estimate the probability and extent of consideration we expect to receive under the contract utilizing either the most-likely amount method or expected amount method, whichever best estimates the amount expected to be received. We then consider any constraints on the variable consideration and includes variable consideration in the transaction price to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We then allocate the transaction price to each performance obligation based on the relative standalone selling price and recognize revenue in the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations that consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We record amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. Deferred revenues expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability. Deferred revenues not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as non-current liabilities.

Research and Development Expense

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue expenses for manufacturing, process development, nonclinical studies and clinical trial activities performed by vendors based upon estimates of the proportion of work completed. We determine the estimates by reviewing contracts,

vendor agreements and purchase orders, and through discussions with our internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our prepaid and accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Stock-Based Compensation

We measure compensation expense for all share-based awards based on the estimated fair value of the share-based awards on the grant date. We use the Black-Scholes option pricing model to value our stock option awards. The fair values of restricted stock units are based on the fair value of the Company's common stock on the date of the grant. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We also grant stock options that vest upon achievement of certain market-based conditions. We use the Monte Carlo pricing model to estimate the fair value of options that have market-based conditions.

The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and, for options granted prior to our IPO, the fair value of the underlying common stock on the date of grant. See Note 10 to our financial statements included elsewhere in this Annual Report on Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the year ended December 31, 2025.

Recent Accounting Pronouncements

See Note 2 to our financial statements found elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our financial statements.

Emerging Growth Company and Smaller Reporting Company Status

The Company was previously an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended ("JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

As of December 31, 2025, the Company ceased to qualify as an emerging growth company. The Company continues to qualify as a "smaller reporting company" as defined in Rule 12b-2 under the Exchange Act and thus will continue to be permitted to make certain reduced disclosures in this Annual Report on Form 10-K and other periodic reports.

We will continue to be a smaller reporting company so long as (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. As long as we remain a smaller reporting company we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended, and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data

SHATTUCK LABS, INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Shattuck Labs, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Shattuck Labs, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, 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 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 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 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 audits 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 audits provide 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/ KPMG LLP

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

Austin, Texas

March 5, 2026

SHATTUCK LABS, INC.
BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 54,192	$ 57,387
Investments	23,873	15,600
Prepaid expenses and other current assets	4,410	6,228
Total current assets	82,475	79,215
Property and equipment, net	6,114	9,812
Investment in related party	1,000	—
Other assets	1,437	2,022
Total assets	$ 91,026	$ 91,049
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,101	$ 2,419
Accrued expenses and other current liabilities	4,951	6,498
Total current liabilities	7,052	8,917
Non-current operating lease liabilities	1,584	2,506
Total liabilities	8,636	11,423
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.0001 par value: 300,000,000 shares authorized, 63,279,843 shares issued and outstanding at December 31, 2025 and 47,714,708 shares issued and outstanding at December 31, 2024	7	5
Additional paid-in capital	512,906	461,339
Accumulated other comprehensive income	6	2
Accumulated deficit	(430,529)	(381,720)
Total stockholders' equity	82,390	79,626
Total liabilities and stockholders' equity	$ 91,026	$ 91,049

See accompanying notes to financial statements

SHATTUCK LABS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Related party license revenue	$ 1,000	$ —
Collaboration revenue	—	5,721
Total revenue	1,000	5,721
Operating expenses:		
Research and development	35,273	67,211
General and administrative	17,235	19,077
Expense from operations	52,508	86,288
Loss from operations	(51,508)	(80,567)
Other income (expense):		
Interest income	2,703	5,174
Other expense	(4)	(17)
Total other income	2,699	5,157
Net loss	$ (48,809)	$ (75,410)
Unrealized gain (loss) on investments	4	(2)
Comprehensive loss	$ (48,805)	$ (75,412)
Net loss per share – basic and diluted	$ (0.70)	$ (1.49)
Weighted-average shares outstanding – basic and diluted	69,584,937	50,758,290

See accompanying notes to financial statements

SHATTUCK LABS, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	47,260,108	$ 5	$ 451,006	$ 4	$ (306,310)	$ 144,705
Exercise of stock options and purchases pursuant to employee stock purchase plan	336,005	—	1,255	—	—	1,255
Issuance of common stock upon settlement of restricted stock units	164,153	—	—	—	—	—
Taxes paid related to net share settlement of restricted stock units	(45,558)	—	(451)	—	—	(451)
Stock-based compensation expense	—	—	9,546	—	—	9,546
Proceeds from sale of common stock	—	—	(17)	—	—	(17)
Unrealized loss on investments	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(75,410)	(75,410)
Balance at December 31, 2024	47,714,708	$ 5	$ 461,339	$ 2	$ (381,720)	$ 79,626
Exercise of stock options and purchases pursuant to employee stock purchase plan	30,275	—	25	—	—	25
Issuance of common stock upon settlement of restricted stock units	236,051	—	—	—	—	—
Taxes paid related to net share settlement of restricted stock units	(54,403)	—	(65)	—	—	(65)
Stock-based compensation expense	—	—	6,995	—	—	6,995
Proceeds from sale of common stock, pre-funded warrants and common stock warrants, net of offering costs	15,225,158	2	44,473	—	—	44,475
Exercise of common stock warrants	128,054	—	139	—	—	139
Unrealized gain on investments	—	—	—	4	—	4
Net loss	—	—	—	—	(48,809)	(48,809)
Balance at December 31, 2025	63,279,843	$ 7	$ 512,906	$ 6	$ (430,529)	$ 82,390

See accompanying notes to financial statements

SHATTUCK LABS, INC.
STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (48,809)	$ (75,410)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	6,995	9,546
Depreciation	3,688	3,829
Non-cash operating lease expense	506	428
Impairment loss of fixed assets	81	222
Non-cash license revenue	(1,000)	—
Net amortization of investments	(453)	(2,151)
Gain on lease modification	(105)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,818	6,367
Other assets	79	90
Accounts payable	(318)	832
Accrued expenses and other current liabilities	(1,442)	(3,368)
Non-current operating lease liabilities	(922)	(900)
Net cash used in operating activities	(39,882)	(60,515)
Cash flows from investing activities:		
Sales and maturities of investments	35,600	85,100
Purchases of investments	(43,416)	(93,552)
Purchase of property and equipment	(71)	(59)
Net cash used in investing activities	(7,887)	(8,511)
Cash flows from financing activities:		
Proceeds from sale of common stock, pre-funded warrants and common stock warrants, net of offering costs	44,475	(17)
Proceeds from the exercise of common stock warrants	139	—
Proceeds from the exercises of stock options and purchases pursuant to employee stock purchase plan	25	1,255
Taxes paid related to net share settlement of equity awards	(65)	(451)
Net cash provided by financing activities	44,574	787
Decrease in cash and cash equivalents	(3,195)	(68,239)
Cash and cash equivalents, beginning of period	57,387	125,626
Cash and cash equivalents, end of period	$ 54,192	$ 57,387

See accompanying notes to financial statements

SHATTUCK LABS, INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization and Description of Business

Shattuck Labs, Inc. (the "Company") was incorporated in 2016 in the State of Delaware and is a biotechnology company specializing in the development of potential treatments for inflammatory and immune-mediated diseases. Shattuck is developing a potentially first-in-class antibody for the treatment of inflammatory bowel disease and other inflammatory and immune-mediated diseases. Shattuck's expertise in protein engineering and the development of novel tumor necrosis factor receptor agonist and antagonist therapeutics come together in its lead program, SL-325, which it believes could be a first-in-class death receptor 3 ("DR3") antagonist antibody designed to achieve best-in-class clinical remission rates due to a more complete and durable blockade of the clinically validated TL1A/DR3 pathway.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $430.5 million as of December 31, 2025. The Company anticipates incurring additional losses and negative cash flows from operations until such time, if ever, that it can generate significant sales of its product candidates currently in development, and is highly dependent on its ability to find additional sources of funding in the form of licensing of its technology, collaboration agreements, and/or public and private debt and equity financings. Adequate additional funding may not be available to the Company on acceptable terms, or at all. The failure to raise funds as and when needed could have a negative impact on the Company's financial condition and ability to pursue its clinical operations, research and development and commercialization of its product candidates. Management believes that the Company's cash and cash equivalents and short-term investments of $78.1 million as of December 31, 2025 are sufficient to fund projected operations of the Company for at least the next twelve months following the date these financial statements are issued.

Global Economic Considerations

The global macroeconomic environment is uncertain and could be negatively affected by, among other things, inflation, slower growth or recession, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, instability, or volatility in the global capital and credit markets, supply chain weaknesses, financial institution instability, changes to fiscal and monetary policy or government budget dynamics, and instability in the geopolitical environment. Such challenges have caused, and may continue to cause, recession fears, high interest rates, foreign exchange volatility, and inflationary pressures. At this time, the Company is unable to quantify the potential effects of this economic instability on its future operations.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses, and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates, if any, are recorded in the period in which they become known and actual results could differ from management's estimates.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received upon the sale of an asset or paid upon the transfer of a liability in an orderly transaction between market participants at the measurement date and in the principal or most advantageous market for that asset or liability. Fair value measurements are classified and disclosed in one of the following categories:

- Level 1: Observable inputs such as quoted prices in active markets for identical assets the reporting entity has the ability to access as of the measurement date;
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values takes into account the market for its financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Management believes that the carrying amounts of the Company's financial instruments, including short-term investments and accounts payable, approximate fair value due to the short-term nature of those instruments.

Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents and short-term investments. The Company maintains its cash and cash equivalents at an accredited financial institution in amounts that exceed federally-insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's short term investments consists of U.S. Treasury securities that management believes protects the Company from risk of default and impairment of value.

All of the Company's revenue in 2025 was derived from a license agreement with Kayak Therapeutics, Inc. ("Kayak").

All of the Company's revenue in 2024 was derived from collaborations with Ono Pharmaceutical Co., Ltd. ("Ono") and ImmunoGen, Inc. ("ImmunoGen") (acquired by AbbVie in February 2024). All services required pursuant to each collaboration agreement were completed by December 31, 2024.

The Company is highly dependent on a limited number of contract development and manufacturing organizations ("CDMOs") to supply drug products for its research and development activities of its programs, including nonclinical studies. The Company is highly dependent on a single CDMO for the supply of cGMP drug product for its clinical trials. These programs could be adversely affected by a significant interruption in the supply of such drug products.

The Company is highly dependent on a limited number of contract research organizations ("CROs") and third-party service providers to manage and support its clinical trials. These programs could be adversely affected by a significant disruption in services provided by these CROs and third parties.

Cash and Cash Equivalents

The Company considers all demand deposits with financial institutions and all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents consisted of $1.9 million held in operating accounts and $52.3 million held in money market funds as of December 31, 2025 and $2.2 million held in operating accounts, and $55.2 million held in money market funds as of December 31, 2024.

Investments

The Company's short-term investments consist of highly-rated U.S. Treasury securities and have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices. Management determines the appropriate classification of its investment securities at the time of purchase. The Company may hold securities with stated maturities greater than one year. All available-for-sale securities are considered available to support current operations and are classified as current assets. Credit impairments for available-for-sale securities are recorded through an allowance rather than a direct write-down of the security and are recorded through a charge to the statements of operations and comprehensive loss. Unrealized gains or losses not related to credit impairments are recorded in accumulated other comprehensive income, a component of stockholders' equity, until realized. The Company reviews available-for-sale debt securities for impairments related to credit losses and other factors each quarter.

The Company has a long-term investment in preferred stock of a privately held company. The investment is accounted for under ASC 321, *Investments in Equity Securities* and is classified as a long-term asset in the accompanying balance sheet as it is not expected to be liquidated within one year. For investments that do not have a readily determinable fair value, the Company applies the measurement alternative, whereby the investment is carried at cost, adjusted for observable price changes in orderly transactions for identical or similar securities of the same issuer and impairment losses, if any.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include prepaid expenses for general business purposes and services used in research projects, which are stated at cost and amortized on a straight-line basis over the related period of benefit. Supplies and materials that have multiple applications for alternative future use are expensed as they are consumed.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of the asset. Expenditures for repairs and maintenance that do not extend the estimated useful life or improve an asset are expensed as incurred. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts, and any resulting gain or loss is included in the statement of operations and comprehensive loss.

Depreciation periods are as follows:

Office equipment	3 years
Furniture and fixtures	5 to 10 years
Lab equipment	5 years
Leasehold improvements	Shorter of lease term or 15 years

Impairment of Long-Lived Assets

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstance indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. An impairment loss is recognized to the extent an asset group is not recoverable and the carrying amount exceeds the projected discounted future cash flows arising from these assets. In the years ended December 31, 2025 and 2024, the Company recorded $0.1 million and $0.2 million, respectively, of impairment losses related to lab equipment that was determined to no longer be needed, which is included in the Company's research and development costs.

Leases

The Company determines if an arrangement is a lease at inception. Right-of-use (“ROU”) 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. The classification of the Company's leases as operating or finance leases, along with the initial measurement and recognition of the associated ROU assets and lease liabilities, are performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The ROU asset is based on the measurement of the lease liability and also includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. The lease terms may include options to extend or terminate the lease when it is reasonably certain the Company will exercise any such options. Rent expense for the Company's operating leases is recognized on a straight-line basis over the lease term. Operating lease ROU assets and long-term operating lease liabilities are presented separately and operating lease liabilities payable in the next 12 months are recorded in accrued expenses and other current liabilities. The Company has elected to not apply the recognition requirement of Accounting Standards Codification (“ASC”) 842, *Leases* of the Financial Accounting Standards Board (“FASB”) to leases with a term of 12 months or less for all classes of assets.

In September 2025, the Company entered into an amendment to its existing office lease agreement to reduce the leased office space. The modification did not result in any other significant changes to the terms of the lease agreement, including lease payments or the lease term associated with the remaining space. In accordance with ASC 842, *Leases*, the Company accounted for the reduction in leased space as a partial termination of the existing lease. As a result, the Company reduced the carrying amounts of both the related ROU asset and lease liability to reflect the decrease in the lease scope, based on the proportionate reduction in the leased area.

The partial termination resulted in the recognition of a gain of approximately $0.1 million, which represents the difference between the reduction in the lease liability and the proportionate reduction in the carrying amount of the ROU asset. The gain was recognized in general and administrative expenses in the accompanying statement of operations for the year ended December 31, 2025. Following the modification, the remaining ROU asset and lease liability continue to be amortized over the remaining lease term, and the Company continues to account for the lease in accordance with ASC 842, *Leases*.

Commitments and Contingencies

The Company follows ASC 450-20, *Contingencies* to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company evaluates the perceived merits of

any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed.

Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed.

Revenue Recognition

Collaboration revenue is recognized in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply and participation on joint steering committees. The Company evaluates the promised goods or services in the contract to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, the Company considers the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, the Company must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

Upon the amendment of an existing agreement, the Company evaluates whether the amendment represents a modification to an existing contract that would be recorded through a cumulative catch-up to revenue, prospective modification, or a separate contract. If it is determined that it is a separate contract, the Company will evaluate the necessary revenue recognition through the five-step process described below.

When the Company concludes that a contract should be accounted for as a combined performance obligation and recognized over time, the Company must then determine the period over which revenue should be recognized and the method by which to measure revenue. The Company generally recognizes revenue using a cost-based input method.

The Company recognizes collaboration revenue in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services when its customer or collaborator obtains control of promised goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the following five steps are performed:

i. identify the contract(s) 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 within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements may consist of a license of, or options to license, the Company's intellectual property and research, development and manufacturing services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources and (ii) are separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable or a combination of both. At

contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most-likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes variable consideration in the transaction price to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations that consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's accompanying balance sheet. Deferred revenues expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability. Deferred revenues not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as non-current liabilities.

The Company's collaboration revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, the Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most-likely amount approach. The Company primarily uses the most-likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. The Company then considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty). The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Services: The Company will record costs associated with development and process optimization activities as research and development expenses in the statements of operations and comprehensive loss consistent with ASC 730, *Research and Development.* The Company considered the guidance in ASC 808, *Collaborative Arrangements* ("ASC 808") and will recognize the payments received from these agreements as revenue when the related costs are incurred.

License Revenue: License revenue is generated from granting third parties rights to certain of the Company's intellectual property, including research, development, and commercialization of specified product candidates. The Company evaluates each licensing arrangement to determine whether the license is distinct from other promised goods or services and whether the arrangement includes multiple performance obligations. If an arrangement includes multiple performance obligations, the transaction price is allocated to each performance obligation based on relative standalone selling prices. Upfront payments, including nonrefundable license fees, are recognized as revenue when the underlying performance obligation is satisfied. Milestone payments that are contingent on the occurrence of a future event are included in the transaction price only when it is

probable that a significant reversal of cumulative revenue will not occur. Sales-based royalties, including milestone payments based on a level of sales, are recognized as revenue when the subsequent sales occur.

The Company may also enter into arrangements that include non-cash consideration, such as equity instruments. In such cases, the Company measures the transaction price at the estimated fair value of the non-cash consideration received at contract inception and recognizes revenue when the performance obligation is satisfied.

Research and Development Costs

Research and development costs are expensed as incurred, and include salaries, stock-based compensation and other personnel-related costs, equipment and supplies, depreciation, nonclinical studies, clinical trials and manufacturing development activities.

A substantial portion of the Company's ongoing research and development activities are conducted by third-party service providers, including CROs and CDMOs. The Company accrues for expenses resulting from obligations under agreements with CROs, CDMOs and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CDMOs and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through an evaluation of the progress or stage of completion of the services. In the event advance payments are made to a CRO, CDMO or outside service provider, the payments will be recorded as a prepaid asset which will be amortized as the contracted services are performed. As actual costs become known, the Company adjusts its accruals and prepaid assets accordingly. Inputs, such as the services performed, the number of patients enrolled or the study duration, may vary from the Company's estimates, resulting in adjustments to research and development expense in future periods. The Company makes significant judgments and estimates in determining the accrual and/or prepaid balance in each reporting period and changes in these estimates may result in material changes to the Company's accruals that could materially affect the Company's results of operations.

Common Stock Warrants and Pre-Funded Warrants

The Company's common stock warrants and pre-funded warrants are classified as a component of permanent stockholders' equity within additional paid-in capital. The common stock warrants and pre-funded warrants are equity classified because they, (i) are freestanding financial instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and, (vi) meet the equity classification criteria. In addition, such common stock warrants and pre-funded warrants do not provide any guarantee of value or return.

Stock-Based Compensation

The Company recognizes the cost of stock-based awards issued to employees and nonemployees as compensation expense on a straight-line basis over the vesting period of the award, net of estimated forfeitures. Forfeiture estimates are based on historical cancellation data. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options. The fair values of restricted stock units ("RSUs") are based on the fair value of the Company's common stock on the date of the grant. The Company also grants stock options that vest upon achievement of certain market-based conditions. The Company uses the Monte Carlo pricing model to estimate the fair value of options that have market-based conditions. The Company adjusts expense for forfeitures in the periods they occur.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial statements and the tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities will be recognized in the period that includes the enactment date. Additionally, any changes in income tax laws are immediately recognized in the year of enactment.

A valuation allowance is established against the deferred tax assets to reduce their carrying value to an amount that is more likely than not to be realized. The deferred tax assets and liabilities are classified as noncurrent along with the related valuation allowance. Due to a lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on the technical merits, as the largest amount of benefits that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the unrecognized tax benefits as a component of income tax expense.

Net Loss Per Share

Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Basic shares outstanding includes the weighted average effect of the Company's outstanding 40,511,011 pre-funded warrants as of December 31, 2025, the exercise of which requires nominal consideration for the delivery of an equal number of shares of common stock. Diluted loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as redeemable convertible preferred stock or convertible notes, if any, stock options and unvested shares of restricted stock, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding as of December 31, 2025 and 2024, as they would be anti-dilutive:

	As of December 31,	
	2025	2024
Common stock warrants	52,507,292	—
Stock options	8,648,715	6,573,172
Unvested restricted stock units	481,177	817,350
	61,637,184	7,390,522

Other Comprehensive Income (Loss)

Other comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive income (loss) is comprised of unrealized gains and losses on short-term investments.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, to require enhanced disclosures that include reportable segment expenses. The amendments in this update provide that a business entity disclose significant segment expenses and segment profit or loss (after significant segment expenses) and allows reporting of additional measures of a segment's profit or loss if used in assessing segment performance. Such disclosures apply to entities with a single reportable segment. These amendments were effective for the Company in 2024 and retrospectively to all prior periods using the significant segment expense categories identified.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments in this update are intended to enhance the transparency and decision usefulness of income tax disclosures primarily through changes to the rate reconciliation and income taxes paid information. This update is effective for annual periods beginning after December 15, 2024, and may be applied prospectively or retrospectively. The Company has retrospectively adopted this ASU in the financial statements for the year ending December 31, 2025. For additional information, see Note 11 Income Taxes.

Recently Issued Accounting Pronouncements

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 ("ASU 2024-03"), which is intended to provide more detailed information about specified categories of expenses (employee compensation, depreciation, and amortization) included in certain expense captions presented on the statement of operations. The guidance in this ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either, (i) prospectively to financial statements issued for periods after the effective date of this ASU or, (ii) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its financial statements and disclosures.

3. Investments

The following table represents the Company’s investments by major security type (amounts in thousands):

	December 31, 2025		
	Amortized Cost	Gross Unrealized Gain	Total Fair Value
Investments:			
U.S. government securities	$ 23,867	$ 6	$ 23,873
Cash Equivalents:			
Money market funds	52,270	—	52,270
Total	$ 76,137	$ 6	$ 76,143

	December 31, 2024		
	Amortized Cost	Gross Unrealized Gain	Total Fair Value
Investments:			
U.S. government securities	$ 15,598	$ 2	$ 15,600
Cash Equivalents:			
Money market funds	55,233	—	55,233
Total	$ 70,831	$ 2	$ 70,833

The Company's money market funds are calculated using level 1 inputs, the Company's U.S. government securities are valued using level 2 inputs. U.S. government securities outstanding as of December 31, 2025 matured in January 2026. There were no impairments of U.S. government securities or money market funds for the years ended December 31, 2025 and 2024.

The Company has a related party investment in a private company’s preferred stock that was recorded at fair value using Level 3 inputs under the measurement alternative. As of December 31, 2025, the Company did not identify any impairment indicators and there have been no observable price changes as of December 31, 2025. The Company had no other investments held at December 31, 2024 other than those included in the table above.

4. Property and Equipment

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

	December 31,	
	2025	2024
Lab equipment	$ 15,267	$ 15,288
Leasehold improvements	6,877	7,097
Furniture and fixtures	452	452
Office equipment	192	192
Property and equipment, gross	22,788	23,029
Less: Accumulated depreciation and amortization	(16,674)	(13,217)
Property and equipment, net	$ 6,114	$ 9,812

Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was $3.7 million and $3.8 million, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (amounts in thousands):

	December 31,	
	2025	2024
Compensation and related benefits	$ 2,767	$ 2,288
Research and development	1,111	2,900
Operating lease liabilities	837	900
Other	236	410
Total accrued expenses and other current liabilities	$ 4,951	$ 6,498

6. Leases

Operating Leases

The Company leases certain office space, laboratory facilities, and equipment in North Carolina and Texas. These leases require monthly lease payments that are subject to annual increases throughout the lease term.

The following table summarizes the Company's recognition of its operating leases (in thousands):

	December 31,	
Balance Sheet Classification	2025	2024
Other assets	$ 1,337	$ 1,843
Accrued expenses and other current liabilities	$ 837	$ 900
Non-current operating lease liabilities	1,584	2,506
Total liabilities	$ 2,421	$ 3,406

The following table summarizes the weighted-average remaining lease term and discount rates for the Company's operating leases:

	December 31,	
	2025	2024
Lease term (years)	2.5	3.5
Discount rate	8.6 %	8.6 %

The Company incurred rent expense for its operating leases of $0.8 million for the years ended December 31, 2025 and 2024 which is included within operating expenses in the statements of operations and comprehensive loss. Cash paid for amounts included in the measurement of operating lease liabilities for the years ended December 31, 2025 and 2024 was $1.1 million and was included in net cash used in operating activities in the statement of cash flows.

In February 2026, the Company renewed its lease for its Austin, Texas office location. The renewal results in future fixed cash payments of $0.2 million in 2027, $0.2 million in 2028, and $0.3 million in 2029.

The maturities of the Company's operating lease liabilities as of December 31, 2025 were as follows (in thousands):

2026	$ 1,006
2027	848
2028	874
2029	—
2030	—
Thereafter	—
Total lease payments	2,728
Less imputed interest	(307)
Lease liability	$ 2,421

7. Commitments and Contingencies

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of December 31, 2025, the Company was not aware of any existing, pending, or threatened legal actions that would have a material impact on the financial position, results of operations, or cash flows of the Company.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which the Company cannot reasonably predict future payment. The Company's contractual obligations result primarily from obligations for various CDMOs and CROs, which include potential payments that may be required under its agreements. The contracts also contain variable costs and milestones that are hard to predict, as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under CDMO and CRO agreements may be different depending on the timing of receipt of goods, services, changes to agreed-upon terms, or amounts for some obligations. Such agreements are cancellable upon written notice by the Company and therefore, are not long-term liabilities.

8. License and Collaboration Revenue

The Company's revenue consisted of the following components for the years ended December 31, 2025 and 2024 (amounts in thousands):

	2025	2024
Related party license revenue	$ 1,000	$ —
Collaboration revenue:		
Ono Pharmaceutical Co., Ltd	—	5,378
ImmunoGen	—	343
License and collaboration revenue	$ 1,000	$ 5,721

Related Party License Revenue

In August 2025, the Company granted Kayak an exclusive license (the "Kayak Agreement") to its oncology-focused TRIM7 program. Pursuant to the Kayak Agreement, as the upfront consideration, the Company received preferred stock in Kayak with a fair market value of $1.0 million and recognized that consideration as license revenue. The Company also subleases certain lab space, office space, and lab equipment to Kayak for one year for total consideration of $0.3 million. Payments received pursuant to the sublease for the year ended December 31, 2025 were $0.1 million and recorded as a reduction to research and development expenses. In November 2025, an officer of the Company was elected to the board of directors of Kayak and as a result, Kayak became a related party.

Pursuant to the Kayak Agreement, the Company is also eligible to receive future payments contingent upon the achievement of specified development, regulatory, and commercial milestones of up to $86.0 million, and tiered royalties on net sales of any commercialized products subject to the Kayak Agreement in the low single digits. Such future payments are considered variable consideration and will be recognized as revenue only when the underlying contingencies are resolved and it is probable that a significant reversal of revenue will not occur.

Collaboration Revenue

The Company recognizes collaboration revenue for collaboration agreements using a cost-based input measure. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to budgeted costs expected to be incurred, and any upfront payments are deferred accordingly.

Ono Pharmaceutical Co., Ltd.

In February 2024, the Company entered into a collaboration and license agreement (the "Ono Agreement") with Ono, pursuant to which the parties collaborated in the research and preclinical development of certain compounds selected by Ono from the Company's pipeline of bifunctional fusion proteins directed toward a pair of prespecified targets for potential treatment of autoimmune and inflammatory diseases. On September 30, 2024, the Company and Ono mutually agreed to terminate the Ono Agreement. Following the mutual termination, the Company is no longer required to satisfy any remaining performance obligations, and will not receive any future research activity reimbursements or upfront milestone or royalty payments from Ono. All options and licenses held by Ono under the Ono Agreement were terminated.

The Ono Agreement was a collaborative arrangement under ASC 808 as both companies were active participants that were exposed to significant risks and rewards. However, since the units of account identified under ASC 808 followed a typical vendor/customer relationship, the Company accounted for the transaction under ASC 606.

Under the Ono Agreement, the Company granted Ono an exclusive option (the "Option") to obtain an exclusive sublicensable license to further research, develop, manufacture, and commercialize products containing the specified bifunctional fusion proteins in any therapeutic area worldwide. The Company determined that the contingent promise to provide the license upon the exercise of the Option should be accounted for as a customer option, and the $2.0 million amount allocated to that Option was recognized as revenue in 2024 pursuant to the termination of the Ono Agreement.

The Company identified a single performance obligation consisting of the preclinical research activities to develop certain bifunctional fusion proteins. The Company recognized $3.4 million in revenue for the preclinical research activities as the services were performed using an inputs method.

ImmunoGen

In 2022, the Company entered into a collaboration agreement with ImmunoGen (the "ImmunoGen Agreement") pursuant to which ImmunoGen agreed to reimburse the Company for $2.0 million of the costs the Company incurred in the Phase 1B combination cohort evaluating SL-172154 in combination with mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer. The Company dosed its first patient with mirvetuximab soravtansine in 2023 and completed all of its obligations under the ImmunoGen Agreement in the second quarter of 2024. The agreement has since been terminated.

9. Equity

The Company is authorized to issue up to 300,000,000 shares of common stock and 10,000,000 shares of preferred stock, all with a par value of $0.0001 per share. The holders of the Company's common stock are entitled to one vote per share on all matters submitted to a vote of stockholders. The Company's common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of the Company's common stock will receive ratably any dividends declared by the Company's board of directors (the "Board") out of funds legally available. In the event of the Company's liquidation, dissolution or winding-up, the holders of the Company's common stock will be entitled to share ratably in all assets remaining after payment of or provision for any liabilities. As of the periods presented, no common stock dividends had been declared by the Board. As of December 31, 2025, none of the 10,000,000 shares of preferred stock were outstanding, and the Company has no present plans to issue any shares of preferred stock.

In December 2023, the Company sold 4,651,163 shares of common stock through an underwritten public offering, and concurrently completed a private placement of 3,100,823 pre-funded warrants. The purchase price per share of common stock was $6.4500, and the purchase price per pre-funded warrant was $6.4499 which was the purchase price per share of common stock, minus the $0.0001 per share exercise price of the pre-funded warrant. Each pre-funded warrant may be exercised for one share of common stock, is immediately exercisable, does not expire, and is subject to a beneficial ownership limitation of 9.99% on a post-exercise basis. As of December 31, 2025, all 3,100,823 pre-funded warrants remain outstanding.

In August 2025, the Company issued and sold 15,225,158 shares of common stock, pre-funded warrants to purchase up to 37,410,188 shares of common stock, and accompanying common stock warrants to purchase up to 52,635,346 shares of common stock in a private placement offering with certain institutional accredited investors. The purchase price of each share of common stock and accompanying common stock warrant was $0.8677, and the purchase price of each pre-funded warrant and accompanying common stock warrant was $0.8676, which was the purchase price per share of common stock and accompanying common stock warrant, minus the $0.0001 per share exercise price of the pre-funded warrants. Each pre-funded warrant may be exercised for one share of common stock, is immediately exercisable, does not expire, and is subject to a beneficial ownership limitations of up to 9.99% on a post-exercise basis. As of December 31, 2025, all 37,410,188 pre-funded warrants remain outstanding.

In January 2026, 3,100,000 pre-funded warrants were exercised.

Each common stock warrant has an exercise price of $1.0846 and is exercisable at any time after the date of issuance for one share of common stock or pre-funded warrant in lieu thereof. The common stock warrants will expire on the 30th day following the date on which the data from the single ascending dose and multiple ascending dose portions of the Company's Phase 1 clinical trial of SL-325, including receptor occupancy and safety data, and the design of the planned Phase 2 clinical trial(s) have been announced publicly. As of December 31, 2025, 52,507,292 common stock warrants remain outstanding.

In January 2026, 4,866,055 common stock warrants were exercised in exchange for 4,866,055 pre-funded warrants with an exercise price of $0.0001 for gross proceeds of $5.3 million.

Two beneficial owners of 10% or more of our common stock participated in the private placement offering with the same terms as all other participants in the offering. Together, the beneficial owners purchased 8,963,785 pre-funded warrants in lieu of common stock and received accompanying common stock warrants to purchase an additional 8,963,785 shares of common stock.

In January 2026, the Company entered into a sales agreement (the "Sales Agreement") with Leerink Partners, LLC (the "Sales Agent"), pursuant to which it may offer and sell up to $75.0 million of shares of its common stock from time to time through an at the market offering facility (the "ATM Facility"). The Sales Agent is generally entitled to compensation at a commission equal to up to 3% of the aggregate gross sales price per share sold under the Sales Agreement. In January 2026, the Company sold 5,000,000 shares of common stock for $4.28 per share for gross proceeds of $21.4 million through the ATM Facility.

10. Stock-Based Compensation and Employee Benefit Plans

2020 Equity Incentive Plan

In September 2020, the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan") which, as of the adoption date, replaced the 2016 Stock Incentive Plan. Under the 2020 Plan, the share reserve automatically increases on January 1st of each year beginning in 2021 and ending with a final increase on January 1, 2030 in an amount equal to 4% of the Company's outstanding shares of common stock on December 31st of the preceding calendar year. The Board may provide that there will be no increase in the share reserve for any such year or that the increase in the share reserve may be smaller than would otherwise occur. As of December 31, 2025, there were 3,741,270 shares of common stock available for future grants. On January 1, 2026, the share reserve automatically increased by 2,531,194 shares. The 2020 Plan permits the granting of options, stock appreciation rights, RSUs, performance stock, and performance cash awards. The terms of the agreements under the 2020 Plan are determined by the Board. The Company's awards generally vest over four years and have a term of 10 years. Periodically, the Company also grants awards that vest based on the Company's stock achieving certain closing share prices for a specified number of consecutive trading days.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the "2020 ESPP") became effective in October 2020. Eligible employees may purchase shares of common stock under the 2020 ESPP at 85% of the lower of the fair market value of the Company's common stock as of the first or the last day of each offering period. Employees are limited to contributing 15% of the employee's eligible compensation and may not purchase more than $25,000 of stock during any calendar year or more than 600 shares during any one purchase period prior to December 31, 2024, and 2,000 shares for purchase periods beginning in 2025. The 2020 ESPP share reserve automatically increases on January 1st of each calendar year, for ten years, commencing on January 1, 2021, in an amount equal to 1% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. The Board may act prior to January 1st of a given year to provide that there will be no January 1st increase of the share reserve for such year or that the increase in the share reserve for such year will be a smaller number of shares of common stock than would otherwise occur pursuant to the preceding sentence. The Board elected not to increase the share reserve for the ESPP on January 1, 2026. As of December 31, 2025, there were 1,629,954 shares available for future purchases. During the years ended December 31, 2025 and 2024, the Company issued 30,275 and 17,246 shares, respectively, of common stock for aggregate cash proceeds of less than $0.1 million each year.

2025 Inducement Grants

In December 2025, the Company issued an inducement grant pursuant to the "inducement exception" provided under Nasdaq Listing Rule 5635(c)(4) ("inducement grants") to a person not previously employed by the Company. The Company may issue additional inducement grants to non-employees or following a bona fide period of non-employment, as an inducement to such persons entering into employment with the Company. Inducement grants must be approved by the Company's compensation committee, and consultants and directors are not eligible to receive inducement grants. Stock options issued as inducement grants generally vest over four years and have a term of 10 years.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 2,951	$ 4,894
General and administrative	4,044	4,652
Total stock-based compensation	$ 6,995	$ 9,546

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

	Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Balance at December 31, 2024	6,573,172	$ 7.19	6.90
Granted	2,999,050	1.28	
Exercised	—	—	
Forfeited	(923,507)	6.23	
Balance at December 31, 2025	8,648,715	$ 5.25	7.06
Vested and expected to vest	3,812,538	$ 2.77	8.87
Exercisable at the end of the period	4,333,697	$ 7.53	5.37

Options granted during the years ended December 31, 2025 and 2024 had weighted-average grant-date fair values of $1.06 and $5.73 per share, respectively. As of December 31, 2025, the unrecognized compensation cost for options issued was $8.0 million and will be recognized over an estimated weighted-average amortization period of 1.17 years. There were no exercises for the year ended December 31, 2025, and the total intrinsic value of options exercised during the year ended December 31, 2024 was $1.7 million. The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2025 was $1.4 million. The aggregate intrinsic value of options outstanding as of December 31, 2025 was $9.2 million.

Restricted Stock Units

The following table summarizes employee RSU activity for the year ended December 31, 2025:

	Awards	Weighted Average Grant Date Fair Value
Unvested RSUs at December 31, 2024	817,350	$ 8.02
Granted	—	—
Vested	(236,051)	7.62
Forfeited	(100,122)	8.36
Balance at December 31, 2025	481,177	8.15

The Company recognized $1.5 million and $2.2 million of stock-based compensation cost related to RSUs as of December 31, 2025 and 2024, respectively. As of December 31, 2025, the unrecognized compensation cost for RSUs issued was $2.4 million and will be recognized over an estimated weighted-average amortization period of 1.01 years. The fair value of RSUs is based on the fair value of the Company's common stock on the date of the grant.

Fair Value of Stock Options and Shares Issued

The Company accounts for stock-based compensation by measuring and recognizing as compensation expense the fair value of all share-based payment awards made to employees, including employee stock options and restricted stock awards. The Company uses the Black-Scholes option pricing model to estimate the fair value of employee stock options that only have service or performance conditions. The inputs to the pricing model require a number of management estimates such as the expected term, volatility, risk-free interest rate and dividend yield. The fair value of stock options was determined using the methods and assumptions discussed below.

- The expected term of employee stock options with service-based vesting is determined using the “simplified” method, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company’s lack of sufficient historical data.
- The expected stock price volatility assumption is based on the historical volatilities of the common stock of a peer group of publicly traded companies as well as the historical volatility of the Company's common stock since the Company began trading subsequent to the Company’s initial public offering (“IPO”) in October 2020 over the period corresponding to the expected life as of the grant date. The historical volatility data was computed using the daily closing prices during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of the Company's stock price becomes available, or until circumstances change, such that the identified entities are no longer comparable companies. In the latter case, other suitable, similar entities whose share prices are publicly available would be utilized in the calculation.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay dividends on its common stock.
- Prior to the Company’s IPO, the Board periodically estimated the fair value of the Company’s common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm. Subsequent to the Company’s IPO, options are issued with a strike price no less than the market price on date of grant.

The grant-date fair value of options calculated using the Black-Scholes option pricing model granted under the Company’s 2020 Plan were estimated using the following weighted-average assumptions:

	Year Ended December 31,	
	2025	2024
2020 Plan		
Expected term - years	5.96	6.02
Expected volatility	102.9 %	97.4 %
Risk-free interest rate	4.3 %	4.2 %
Expected dividends	$ —	$ —

The grant-date fair value of shares issued calculated using the Black-Scholes option pricing model under the Company’s 2020 ESPP were estimated using the following weighted-average assumptions:

	Year Ended December 31,	
	2025	2024
2020 ESPP		
Expected term - years	0.5	0.5
Expected volatility	105.2 %	115.1 %
Risk-free interest rate	4.2 %	5.1 %
Expected dividends	$ —	$ —

Employee Benefit Plans

The Company sponsors a 401(k) retirement plan in which substantially all of its full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. The Company made matching contributions of $0.4 million and $0.6 million to the plan for the years ended December 31, 2025 and 2024, respectively.

11. Income Taxes

The Company recorded no federal provision for income taxes as of December 31, 2025 and 2024 due to reported net losses since inception. A reconciliation of the expected income tax expense (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows for the years ended December 31, 2025 and 2024 (amounts in thousands):

	Year Ended December 31,			
	2025		2024	
	Amount	Rate	Amount	Rate
Income tax benefit computed at federal statutory tax rate	$ (10,250)	21.0 %	$ (15,809)	21.0 %
Change in valuation allowance	11,064	(22.7)%	19,231	(25.5)%
Tax credits				
R&D credit	(1,124)	2.3 %	(2,819)	3.7 %
Prior year R&D credit adjustment	71	(0.1)%	(1,216)	1.6 %
Nontaxable/nondeductible	259	(0.5)%	360	(0.5)%
Change in unrecognized tax benefits	(14)	— %	243	(0.3)%
Other	(6)	— %	10	— %
Income tax benefit	$ —	— %	$ —	— %

Cash tax payments are considered immaterial to the financial statements for both federal and state purposes.

Significant components of the Company's deferred tax assets and liabilities are as follows (amounts in thousands):

	December 31,	
	2025	2024
Deferred tax asset:		
Net operating loss carryforwards	$ 52,705	$ 41,131
Accrued expenses and other	856	1,142
Stock compensation	4,943	3,727
Credit carryforwards	18,473	17,406
Capital loss carryforwards	556	576
Capitalized R&D expense	29,415	32,121
Lease liabilities	508	715
Gross deferred tax asset	107,456	96,818
Less valuation allowance	(106,686)	(95,622)
Net deferred tax asset	770	1,196
Deferred tax liability:		
Depreciation and amortization	(195)	(533)
Prepaid expenses	(294)	(276)
Lease assets	(281)	(387)
Total deferred tax liability	(770)	(1,196)
Total net deferred tax asset	$ —	$ —

The Company has established a valuation allowance equal to the net deferred tax asset due to uncertainties regarding the realization of the deferred tax asset based on the Company's lack of earnings history. The valuation allowance increased by $11.1 million and $19.2 million during the years ended December 31, 2025 and 2024, respectively, primarily due to continuing loss from operations, general business credit carryforwards, section 174 research and development capitalization and accrued expenses.

As of December 31, 2025 and 2024, the Company had gross U.S. net operating loss ("NOL") carryforwards of $251.0 million and $195.8 million, respectively. Additionally, as of December 31, 2025 and 2024, the Company had gross U.S. tax credit carryforwards of $23.0 million and $21.6 million, respectively. As of December 31, 2025 and 2024, the Company had gross state NOL carryforwards of $0.1 million and $0.0 million, respectively. As of December 31, 2025 and 2024, the Company capital loss carryforwards of $2.6 million and $2.7 million, respectively. The capital loss and tax credit carryforwards as of December 31, 2024 began to expire in 2025. The NOL, capital loss, and credit carryforwards are subject to Internal Revenue Service adjustments until the statute closes on the year the NOL or credit carryforwards are utilized.

Section 382 of the Internal Revenue Code limits the utilization of U.S. NOLs following a change of control. On August 26, 2025, the Company sold shares of the Company's common stock and pre-funded warrants ("PFW") in a private placement investment in public entity ("PIPE") transaction. As a result, the Company completed a Section 382 study to determine if a ownership change resulted due to these transactions. The 382 study performed determined that an ownership change occurred on August 26, 2025 resulting in a limitation on the Company's deferred tax assets. Since the Company is in a full valuation allowance position and is expected to continue to be in a valuation allowance position, this determination did not have an immediate effect on the Company's financial statements as all tax attributes are fully valued.

A reconciliation of the Company's liability for unrecognized tax benefits is as follows (amounts in thousands):

	Year Ended December 31,	
	2025	2024
Balance, beginning of the year	$ 4,206	$ 3,258
Increase for tax positions related to the current year	281	705
(Decrease) increase for tax positions related to prior years	(14)	243
Balance, end of year	$ 4,473	$ 4,206

All of the Company's gross unrecognized tax benefits, if recognized, would affect its effective tax rate. The Company does not expect unrecognized tax benefits to decrease within the next twelve months due to the lapse of statute limitations. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2025, the Company has not accrued any interest or penalties related to unrecognized tax benefits.

The Company files income tax returns in the U.S. and state jurisdictions. The Company is subject to examination by taxing authorities in its significant jurisdictions for the 2021, 2022 and 2023 tax years. There are currently no federal or state income tax audits in progress.

12. Discontinuation of SL-172154 Clinical Development

On October 1, 2024, the Company approved a restructuring plan to prioritize the development of the Company's DR3 program. The restructuring plan optimized the Company's cost structure by aligning the size and structure of its workforce with the Company's current goals and strategy. The organizational realignment included the discontinuation the Company's SL-172154 program in view of overall survival data readouts from its clinical trial in higher-risk myelodysplastic syndromes and acute myeloid leukemia. Approximately 40% of Shattuck's workforce was impacted by the changes. As a result of this restructuring, the Company incurred one-time termination benefits of $1.0 million that was recorded in the research and development and general and administrative line items in the Company's statements of operations and comprehensive loss. The Company recognized this expense in the fourth quarter of 2024 and paid $0.9 million in 2024 and $0.1 million in January 2025.

13. Segment Reporting

The Company has one reportable and operating segment, which is engaged in the business of drug discovery and development. The Company's chief operating decision maker ("CODM") is the Company's chief executive officer. The CODM uses the Company's net loss to monitor actual results versus the budget in assessing segment performance and the allocation of resources. The measure of segment assets is reported on the balance sheets as total assets. Accounting policies for segment reporting are the same as the accounting policies disclosed in Note 2.

The following table sets forth information about the Company's single reportable segment and the significant expenses reviewed by the CODM, including a reconciliation to net loss (in thousands):

	Year Ended December 31,	
	2025	2024
License and collaboration revenue	$ 1,000	$ 5,721
Operating expenses:		
Research and development:		
SL-325[1]	10,777	4,574
SL-172154	2,637	27,608
Other research and development[2]	9,776	16,010
Research and development non-equity compensation	9,132	14,125
Research and development equity compensation	2,951	4,894
Total research and development	35,273	67,211
General and administrative expenses:		
General and administrative non-equity compensation	5,302	5,858
General and administrative equity compensation	4,044	4,653
Other general and administrative including legal and accounting fees, facilities, insurance, travel and depreciation	7,889	8,566
Total general and administrative	17,235	19,077
Expense from operations	52,508	86,288
Loss from operations	(51,508)	(80,567)
Other Income (expense):		
Interest income	2,703	5,174
Other expense	(4)	(17)
Total other income	2,699	5,157
Net loss	$ (48,809)	$ (75,410)

[1] Expenses for SL-325 that were incurred prior to it being nominated a product candidate are included in "other research and development".

[2] Other research and development expense includes technical operations expense of $2.8 million and $4.2 million, other research and development expense (primarily includes research activities for other pipeline compounds and facility expenses) of $3.4 million and $8.2 million and depreciation expense of $3.5 million and $3.6 million for the years ended December 31, 2025 and 2024, respectively.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. Based on this evaluation of our disclosure controls and procedures as of December 31, 2025, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our

principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Annual Report on Internal Control Over Financial Reporting

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

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 our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of Registered Public Accounting Firm

As a smaller reporting company and non-accelerated filer, as defined in the Exchange Act, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, our independent registered public accounting firm has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during fourth quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

Item 9B. Other Information

Trading Plans

During the quarter ended December 31, 2025, no director or Section 16 officer adopted or terminated any Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

Part III.

Item 10. Directors, Executive Officers and Corporate Governance

Except as provided below, the information required by this item is incorporated herein by reference to our Proxy Statement relating to our 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, including under the headings "Information Regarding Director Nominees and Continuing Directors," "Corporate Governance," "Insider Trading Policy," "Executive Officers," and, as applicable, "Delinquent Section 16(a) Reports."

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is available on our website located at ir.shattucklabs.com, under "Governance." We intend to disclose on our website future amendments to certain provisions of the code, and waivers of the code granted to executive officers and directors, that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our 2026 Proxy Statement, including under the headings "Executive Compensation", "Director Compensation" and "Compensation Committee Interlock."

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

The information required by this item is incorporated herein by reference to our 2026 Proxy Statement, including under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

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

The information required by this item is incorporated herein by reference to our 2026 Proxy Statement, including under the headings "Corporate Governance" and "Certain Relationships and Related Party Transactions."

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to our 2026 Proxy Statement, including under the heading "Ratification of Independent Auditor Selection."

Part IV.

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

(a) Financial Statements.

See Index to Financial Statements at Part II, Item 8 “Financial Statements and Supplementary Data.”

(b) Financial Statement Schedules.

No financial statement schedules are provided because the information called for is not required or is included in the financial statements or the notes thereto.

(c) Exhibits.

The following exhibits are filed (or incorporated by reference herein) as part of this Annual Report on Form 10-K:

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of Shattuck Labs, Inc. (incorporated by reference from Exhibit 3.1 to the Company’s Current Report on Form 8-K filed on October 14, 2020 (Commission File No. 001-39593)).
3.2	Amended and Restated Bylaws of Shattuck Labs, Inc. (incorporated by reference from Exhibit 3.2 to the Company’s Current Report on Form 8-K filed on October 14, 2020 (Commission File No. 001-39593)).
4.1	Form of common stock certificate of the Company (incorporated by reference from Exhibit 4.1 of the Company’s Amendment No. 1 to Registration Statement on Form S-1 filed on October 05, 2020 (Commission File No. 333-248918)).
4.2	Description of Securities (incorporated by reference from Exhibit 4.3 of the Company’s Annual Report on Form 10-K filed on March 16, 2021 (Commission File No.: 001-39593).
4.3	Form of Pre-Funded Warrant (incorporated by reference from Exhibit 4.1 of the Company’s Current Report on Form 8-K filed on December 22, 2023 (Commission File No. 001-39593)).
4.4	Form of Pre-Funded Warrant (incorporated by reference from Exhibit 4.1 of the Company’s Current Report on Form 8-K filed on August 5, 2025 (Commission File No. 001-39593)).
4.5	Form of Common Warrant (incorporated by reference from Exhibit 4.2 of the Company’s Current Report on Form 8-K filed on August 5, 2025 (Commission File No. 001-39593)).
10.1+*	Form of Indemnification Agreement for directors and executive officers.
10.2+	Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Taylor Schreiber (incorporated by reference from Exhibit 10.4 to the Company’s Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.3+	Amendment No. 1 to Employment Agreement, dated March 27, 2020, by and between Shattuck Labs, Inc. and Taylor Schreiber (incorporated by reference from Exhibit 10.5 to the Company’s Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.4+	Amendment No. 2 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Taylor Schreiber (incorporated by reference from Exhibit 10.6 of the Company’s Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593).
10.5+	Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Arundathy Nirmalini Pandite (incorporated by reference from Exhibit 10.6 to the Company’s Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.6+	Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Arundathy Nirmalini Pandite (incorporated by reference from Exhibit 10.8 of the Company’s Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593).
10.07+	Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Andrew R. Neill (incorporated by reference from Exhibit 10.8 to the Company’s Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.08+	Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Andrew R. Neill (incorporated by reference from Exhibit 10.12 of The Company’s Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593).

10.09+	Employment Agreement, dated December 9, 2019, by and between Shattuck Labs, Inc. and Casi DeYoung (incorporated by reference from Exhibit 10.13 of the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593).
10.10+	Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Casi DeYoung (incorporated by reference from Exhibit 10.14 of the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593).
10.11+	Employment Agreement, dated June 1, 2021, by and between Shattuck Labs, Inc. and Abhinav Shukla (incorporated by reference from Exhibit 10.11 of the Company's Annual Report on Form 10-K filed on February 29, 2024 (Commission File No. 001-39593)).
10.12+	2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.9 of the Company's Amendment No. 1 to Registration Statement on Form S-1 filed on October 5, 2020 (Commission File No. 333-248918)).
10.13+	2020 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.10 of the Company's Amendment No. 1 to Registration Statement on Form S-1 filed on October 5, 2020 (Commission File No. 333-248918)).
10.14+	Form of Stock Option Grant Notice and Stock Option Agreement for Executives under the 2020 Employment Incentive Plan (incorporated by reference from Exhibit 10.14 of the Company's Annual Report on Form 10-K filed on February 29, 2024 (Commission File No. 001-39593)).
10.15+	Form of Stock Option Grant Notice and Stock Option Agreement for Board of Directors under the 2020 Employment Incentive Plan (incorporated by reference from Exhibit 10.15 of the Company's Annual Report on Form 10-K filed on February 29, 2024 (Commission File No. 001-39593)).
10.16+	Form of Restricted Stock Unit Grant Notice and Stock Option Agreement under the 2020 Employment Incentive Plan (incorporated by reference from Exhibit 10.16 of the Company's Annual Report on Form 10-K filed on February 29, 2024 (Commission File No. 001-39593)).
10.17+*	Non-Employee Director Compensation Policy, as amended on February 10, 2026.
10.18	Lease Agreement, dated April 17, 2018, between Shattuck Labs, Inc. and Parmer RTP, LLC, as amended (incorporated by reference from Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.19†	Lease Agreement, dated January 8, 2021, between Shattuck Labs, Inc. and International Bank of Commerce, Laredo, Texas. incorporated by reference from Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)).
10.20	Sales Agreement, dated January 22, 2026, between Shattuck Labs, Inc. and Leerink Partners LLC (incorporated by reference from Exhibit 1.1 of Shattuck's Current Report on Form 8-K filed on January 22, 2026 (Commission File No. 001-39593)).
10.21	Registration Rights Agreement, dated December 21, 2023, by and between Shattuck Labs, Inc. and the several purchasers signatory thereto (incorporated by reference from Exhibit 10.2 of Shattuck's Current Report on Form 8-K filed on December 22, 2023 (Commission File No. 001-39593)).
10.22	Master Services Agreement, dated November 18, 2024, by and between Shattuck Labs, Inc and Kemwell Biopharma Private, Ltd.
19.1*	Insider Trading Policy as amended on November 5, 2025.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32.1#	Certification of the principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) under the Securities Exchange Act of 1934.
97.1*	Incentive Compensation Clawback Policy (incorporated by reference from Exhibit 97.1 of the Company's Annual Report on Form 10-K filed on February 29, 2024 (Commission File No. 001-39593)).
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document

101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, formatted in Inline XBRL (included in Exhibit 101).

* Filed herewith.
+ Indicates management contract or compensatory plan.
† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
# The certifications on Exhibit 32 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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, the Registrant has duly caused this Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on this 5th day of March 2026.

Shattuck Labs, Inc.

Date: March 5, 2026

By: /s/ Dr. Taylor Schreiber
Dr. Taylor Schreiber
Chief Executive Officer
(principal executive officer)

Date: March 5, 2026

By: /s/ Andrew R. Neill
Andrew R. Neill
Chief Financial Officer
(principal financial and accounting officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dr. Taylor Schreiber, Andrew R. Neill and Stephen Stout, and each of them, as true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for them and in their name, place and stead, in any and all capacities, to sign in any and all capacities (including, without limitation, the capacities listed below), this Annual Report on Form 10-K, any and all amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, and hereby grants to such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and anything necessary to be done to enable the registrant to comply with the provisions of the Securities Exchange Act and all the requirements of the Securities and Exchange Commission, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her 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, this Annual Report on Form 10-K has been signed below by the following persons in the capacities and on the dates set forth opposite their names.

Signature	Title	Date
/s/ Dr. Taylor Schreiber Dr. Taylor Schreiber	Chief Executive Officer and Director (*principal executive officer*)	March 5, 2026
/s/ Andrew R. Neill Andrew R. Neill	Chief Financial Officer (*principal financial and accounting officer*)	March 5, 2026
/s/ Dr. George Golumbeski Dr. George Golumbeski	Chairman of the Board	March 5, 2026
/s/ Helen M. Boudreau Helen M. Boudreau	Director	March 5, 2026
/s/ Dr. Neil Gibson Dr. Neil Gibson	Director	March 5, 2026
/s/ Mona Ashiya Mona Ashiya	Director	March 5, 2026
/s/ Dan Baker Dan Baker	Director	March 5, 2026
/s/ Dr. Clay Siegall Dr. Clay Siegall	Director	March 5, 2026

INDEMNIFICATION AGREEMENT

This Indemnification Agreement (this "Agreement") is entered into as of _____ by and between Shattuck Labs, Inc., a Delaware corporation (the "Company"), and _____ (the "Indemnitee") and shall be deemed effective upon the earliest date that the Indemnitee is duly elected or appointed as a director or officer of the Company.

RECITALS

WHEREAS, the Board of Directors has determined that the inability to attract and retain qualified persons as directors and officers is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there shall be adequate certainty of protection through insurance and indemnification against risks of claims and actions against them arising out of their service to and activities on behalf of the Company;

WHEREAS, the Company has adopted provisions in its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and Amended and Restated Bylaws ("Bylaws") providing for indemnification and advancement of expenses of its directors and officers to the fullest extent authorized by the General Corporation Law of the State of Delaware (the "DGCL"), and the Company wishes to clarify and enhance the rights and obligations of the Company and the Indemnitee with respect to indemnification and advancement of expenses;

WHEREAS, in order to induce and encourage highly experienced and capable persons such as the Indemnitee to serve and continue to serve as directors and officers of the Company and in any other capacity with respect to the Company as the Company may request, and to otherwise promote the desirable end that such persons shall resist what they consider unjustified lawsuits and claims made against them in connection with the good faith performance of their duties to the Company, with the knowledge that certain costs, judgments, penalties, fines, liabilities, and expenses incurred by them in their defense of such litigation are to be borne by the Company and they shall receive the maximum protection against such risks and liabilities as may be afforded by applicable law, the Board of Directors of the Company has determined that the following Agreement is reasonable and prudent to promote and ensure the best interests of the Company and its stockholders; and

WHEREAS, the Company desires to have the Indemnitee serve or continue to serve as a director or officer of the Company and in any other capacity with respect to the Company as the Company may request, as the case may be, free from undue concern for unpredictable, inappropriate, or unreasonable legal risks and personal liabilities by reason of the Indemnitee acting in good faith in the performance of the Indemnitee's duty to the Company; and the Indemnitee desires to continue so to serve the Company, provided, and on the express condition, that he or she is furnished with the protections set forth hereinafter.

AGREEMENT

NOW, THEREFORE, in consideration of the Indemnitee's service or continued service as a director or officer of the Company, the parties hereto agree as follows:

1. Definitions. For purposes of this Agreement:

(a) A "Change in Control" will be deemed to have occurred if, with respect to any particular 24-month period, the individuals who, at the beginning of such 24-month period, constituted the Board of Directors of the Company (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors; provided, however, that any individual becoming a director subsequent to the beginning of such 24-month period whose election, or nomination for election by the stockholders of the Company, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of

office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board of Directors.

(b) "Disinterested Director" means a director of the Company who is not or was not a party to the Proceeding in respect of which indemnification is being sought by the Indemnitee.

(c) "Expenses" includes, without limitation, expenses incurred in connection with the defense or settlement of any action, suit, arbitration, alternative dispute resolution mechanism, inquiry, judicial, administrative, or legislative hearing, investigation, or any other threatened, pending, or completed proceeding, whether brought by or in the right of the Company or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative, or other nature, attorneys' fees, witness fees and expenses, fees and expenses of accountants and other advisors, retainers and disbursements and advances thereon, the premium, security for, and other costs relating to any bond (including cost bonds, appraisal bonds, or their equivalents), and any expenses of establishing a right to indemnification or advancement under this Agreement, but shall not include the amount of judgments, fines, ERISA excise taxes, or penalties actually levied against the Indemnitee, or any amounts paid in settlement by or on behalf of the Indemnitee.

(d) "Independent Counsel" means a law firm or a member of a law firm that neither is presently nor in the past five years has been retained to represent (i) the Company or the Indemnitee in any matter material to either such party or (ii) any other party to the Proceeding giving rise to a request for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or the Indemnitee in an action to determine the Indemnitee's right to indemnification under this Agreement.

(e) "Proceeding" means any action, suit, arbitration, alternative dispute resolution mechanism, inquiry, judicial, administrative, or legislative hearing, investigation, or any other threatened, pending, or completed proceeding, whether brought by or in the right of the Company or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative, or other nature, to which the Indemnitee was or is a party or is threatened to be made a party or is otherwise involved in by reason of the fact that the Indemnitee is or was a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee of the Company is or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan (such status, the Indemnitee's "Corporate Status"), or by reason of anything done or not done by the Indemnitee in any such capacity, whether or not the Indemnitee is serving in such capacity at the time any expense, liability, or loss is incurred for which indemnification or advancement can be provided under this Agreement.

2. Service by the Indemnitee. The Indemnitee shall serve and/or continue to serve as a director or officer of the Company faithfully and to the best of the Indemnitee's ability so long as the Indemnitee is duly elected or appointed and until such time as the Indemnitee's successor is elected and qualified or the Indemnitee is removed as permitted by applicable law or tenders a resignation in writing.

3. Indemnification and Advancement of Expenses. The Company shall indemnify and hold harmless the Indemnitee, and shall pay to the Indemnitee in advance of the final disposition of any Proceeding all Expenses incurred by the Indemnitee in defending any such Proceeding, to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, all on the terms and conditions set forth in this Agreement. Without diminishing the scope of the rights provided by this Section, the rights of the Indemnitee to indemnification and advancement of Expenses provided hereunder shall include but shall not be limited to those rights hereinafter set forth, except that no indemnification or advancement of Expenses shall be paid to the Indemnitee:

(a) to the extent expressly prohibited by applicable law or the Certificate of Incorporation and Bylaws of the Company;

(b) for and to the extent that payment is actually made to the Indemnitee under a valid and collectible insurance policy or under a valid and enforceable indemnity clause, provision of the certificate of incorporation or bylaws, or agreement of the Company or any other company or other enterprise (and the Indemnitee shall reimburse the Company for any amounts paid by the Company and subsequently so recovered by the Indemnitee); or

(c) in connection with an action, suit, or proceeding, or part thereof voluntarily initiated by the Indemnitee (including claims and counterclaims, whether such counterclaims are asserted by (i) the Indemnitee, or (ii) the Company in an action, suit, or proceeding initiated by the Indemnitee), except a judicial proceeding pursuant to Section 11 to enforce rights under this Agreement, unless (A) the action, suit, or proceeding, or part thereof, was authorized or ratified by the Board of Directors of the Company or the Board of Directors otherwise determines that indemnification or advancement of expenses is appropriate or (B) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

4. Action or Proceedings Other than an Action by or in the Right of the Company. Except as limited by Section 3 above, the Indemnitee shall be entitled to the indemnification rights provided in this Section if the Indemnitee was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any Proceeding (other than an action by or in the right of the Company) by reason of the Indemnitee's Corporate Status, or by reason of anything done or not done by the Indemnitee in any such capacity. Pursuant to this Section, the Indemnitee shall be indemnified against all expense, liability, and loss (including judgments, fines, ERISA excise taxes or penalties, amounts paid in settlement by or on behalf of the Indemnitee, and Expenses) actually and reasonably incurred by the Indemnitee, or on behalf of the Indemnitee, in connection with such Proceeding, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe his or her conduct was unlawful.

5. Indemnity in Proceedings by or in the Right of the Company. Except as limited by Section 3 above, the Indemnitee shall be entitled to the indemnification rights provided in this Section if the Indemnitee was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any Proceeding brought by or in the right of the Company to procure a judgment in its favor by reason of the Indemnitee's Corporate Status, or by reason of anything done or not done by the Indemnitee in any such capacity. Pursuant to this Section, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee, or on behalf of the Indemnitee, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, that no such indemnification shall be made in respect of any claim, issue, or matter as to which the DGCL expressly prohibits such indemnification by reason of any adjudication of liability of the Indemnitee to the Company, unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the Indemnitee is entitled to indemnification for such expense, liability, and loss as such court shall deem proper.

6. Indemnification for Costs, Charges, and Expenses of Successful Party. Notwithstanding any limitations of Sections 3(c), 4, and 5 above, to the extent that the Indemnitee has been successful, on the merits or otherwise, in whole or in part, in defense of any Proceeding, or in defense of any claim, issue, or matter therein, including, without limitation, the dismissal of any action without prejudice, or if it is ultimately determined, by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal, that the Indemnitee is otherwise entitled to be indemnified against Expenses, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee in connection therewith. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

7. Partial Indemnification. If the Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of the expense, liability, and loss (including judgments, fines, ERISA excise taxes or penalties, amounts paid in settlement by or on behalf of the Indemnitee, and Expenses) actually and reasonably incurred in connection with any Proceeding, or in connection with any judicial proceeding pursuant to Section 11 to enforce rights under this Agreement, but not, however, for all of the total amount thereof, the Company shall nevertheless indemnify the Indemnitee for the portion of such expense, liability, and loss actually and reasonably incurred to which the Indemnitee is entitled.

8. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the maximum extent permitted by the DGCL, the Indemnitee shall be entitled to indemnification against all Expenses actually and reasonably incurred by the Indemnitee or on the Indemnitee's behalf if the Indemnitee appears as a

witness, responds to a discovery request or otherwise incurs legal expenses as a result of or related to the Indemnitee's service as a director or officer of the Company, in any threatened, pending, or completed action, suit, arbitration, alternative dispute resolution mechanism, inquiry, judicial, administrative, or legislative hearing, investigation, or any other threatened, pending, or completed proceeding, whether of a civil, criminal, administrative, legislative, investigative, or other nature, to which the Indemnitee neither is, nor is threatened to be made, a party.

9. Determination of Entitlement to Indemnification. To receive indemnification under this Agreement, the Indemnitee shall submit a written request to the Secretary of the Company. Such request shall include documentation or information that is necessary for such determination and is reasonably available to the Indemnitee. Notwithstanding the foregoing, any failure of the Indemnitee to provide such a request to the Company, or to provide such a request in a timely fashion, shall not relieve the Company of any liability that it may have to the Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company. Upon receipt by the Secretary of the Company of a written request by the Indemnitee for indemnification pursuant to this Agreement, the entitlement of the Indemnitee to indemnification, to the extent not provided pursuant to the terms of this Agreement, shall be determined by the following person or persons who shall be empowered to make such determination (as selected by the Board of Directors, except with respect to Section 9(e) below): (a) the Board of Directors by a majority vote of Disinterested Directors, whether or not such majority constitutes a quorum; (b) a committee of Disinterested Directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; (c) if there are no Disinterested Directors, or if the Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee; (d) the stockholders of the Company; or (e) in the event that a Change in Control has occurred, at the option of the Indemnitee, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee. Such Independent Counsel shall be selected by the Board of Directors and approved by the Indemnitee, except that in the event that a Change in Control has occurred, Independent Counsel shall be selected by the Indemnitee. Upon failure of the Board of Directors so to select such Independent Counsel or upon failure of the Indemnitee so to approve (or so to select, in the event a Change in Control has occurred), such Independent Counsel shall be selected upon application to a court of competent jurisdiction. The determination of entitlement to indemnification shall be made and, unless a contrary determination is made, such indemnification shall be paid in full by the Company not later than the earlier of (i) 60 calendar days after receipt by the Secretary of the Company of a written request for indemnification and (ii) 10 calendar days after determination has been made that the Indemnitee is entitled to indemnification pursuant to Section 10 of this Agreement. If the person making such determination shall determine that the Indemnitee is entitled to indemnification as to part (but not all) of the application for indemnification, such person shall reasonably prorate such partial indemnification among the claims, issues, or matters at issue at the time of the determination.

10. Presumptions and Effect of Certain Proceedings. The Secretary of the Company shall, promptly upon receipt of the Indemnitee's written request for indemnification, advise in writing the Board of Directors or such other person or persons empowered to make the determination as provided in Section 9 that the Indemnitee has made such request for indemnification. Upon making such request for indemnification, the Indemnitee shall be presumed to be entitled to indemnification hereunder and the Company shall have the burden of proof in making any determination contrary to such presumption. If the person or persons so empowered to make such determination shall have failed to make the requested determination with respect to indemnification within 60 calendar days after receipt by the Secretary of the Company of such request, a requisite determination of entitlement to indemnification shall be deemed to have been made and the Indemnitee shall be absolutely entitled to such indemnification, absent actual fraud in the request for indemnification. The termination of any Proceeding described in Sections 4 or 5 by judgment, order, settlement, or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself (a) create a presumption that the Indemnitee did not act in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, or with respect to any criminal Proceeding, had reasonable cause to believe his or her conduct was unlawful or (b) otherwise adversely affect the rights of the Indemnitee to indemnification except as may be provided herein.

11. Remedies of the Indemnitee in Cases of Determination Not to Indemnify or to Advance Expenses; Right to Bring Suit. In the event that a determination is made that the Indemnitee is not entitled to indemnification hereunder or if payment is not timely made following a determination of entitlement to indemnification pursuant to Sections 9

and 10, or if an advancement of Expenses is not timely made pursuant to Section 16, the Indemnitee may at any time thereafter bring suit against the Company seeking an adjudication of entitlement to such indemnification or advancement of Expenses, and any such suit shall be brought in the Court of Chancery of the State of Delaware unless, if the Indemnitee is an employee of the Company, otherwise required by the law of the state in which the Indemnitee primarily resides and works. The Company shall not oppose the Indemnitee's right to seek any such adjudication. In any suit brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the Indemnitee to enforce a right to an advancement of Expenses), it shall be a defense that the Indemnitee did not act in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal Proceeding, had no reasonable cause to believe his or her conduct was unlawful. Further, in any suit brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the Company shall be entitled to recover such Expenses upon a final judicial decision of a court of competent jurisdiction from which there is no further right to appeal that the Indemnitee has not met the standard of conduct described above. Neither the failure of the Company (including the Disinterested Directors, a committee of Disinterested Directors, Independent Counsel, or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the standard of conduct described above, nor an actual determination by the Company (including the Disinterested Directors, a committee of Disinterested Directors, Independent Counsel, or its stockholders) that the Indemnitee has not met the standard of conduct described above shall create a presumption that the Indemnitee has not met the standard of conduct described above, or, in the case of such a suit brought by the Indemnitee, be a defense to such suit. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of Expenses hereunder, or brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Section 11 or otherwise shall be on the Company. If a determination is made or deemed to have been made pursuant to the terms of Section 9 or 10 that the Indemnitee is entitled to indemnification, the Company shall be bound by such determination and is precluded from asserting that such determination has not been made or that the procedure by which such determination was made is not valid, binding, and enforceable. The Company further agrees to stipulate in any court pursuant to this Section 11 that the Company is bound by all the provisions of this Agreement and is precluded from making any assertions to the contrary. If the court shall determine that the Indemnitee is entitled to any indemnification or advancement of Expenses hereunder, the Company shall pay all Expenses actually and reasonably incurred by the Indemnitee in connection with such adjudication (including, but not limited to, any appellate proceedings) to the fullest extent permitted by law, and in any suit brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the Company shall pay all Expenses actually and reasonably incurred by the Indemnitee in connection with such suit to the extent the Indemnitee has been successful, on the merits or otherwise, in whole or in part, in defense of such suit, to the fullest extent permitted by law.

12. Non-Exclusivity of Rights; Survival of Rights; Insurance; Subrogation.

(a) The rights provided by this Agreement shall not be deemed exclusive of any other rights to which the Indemnitee may at any time be entitled under applicable law, the certificate of incorporation or the bylaws of the Company (including the Certificate Incorporation or Bylaws), any agreement, a vote of stockholders, a resolution of the Board of Directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision of this Agreement shall limit or restrict any right of the Indemnitee under this Agreement in respect of any action taken or omitted by the Indemnitee in his or her Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL, whether by statute or judicial decision, permits greater indemnification than would be afforded under the current certificate of incorporation or bylaws of the Company and this Agreement, it is the intent of the parties hereto that the Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person serves at the request of the Company, the

Company shall obtain coverage for the Indemnitee under such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any other director (if the Indemnitee is a director), or officer (if the Indemnitee is not a director but is an officer), of the Company under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms of this Agreement, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all commercially reasonable steps to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of the Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company effectively to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that the Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to the Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount the Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.

13. Expenses to Enforce Agreement. In the event that the Indemnitee is subject to or intervenes in any action, suit, or proceeding in which the validity or enforceability of this Agreement is at issue or seeks an adjudication to enforce the Indemnitee's rights under, or to recover damages for breach of, this Agreement, the Indemnitee, if the Indemnitee prevails in whole or in part in such action, suit, or proceeding, shall be entitled to recover from the Company and shall be indemnified by the Company against any Expenses actually and reasonably incurred by the Indemnitee in connection therewith.

14. Continuation of Indemnity. All agreements and obligations of the Company contained herein shall continue during the period the Indemnitee is a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee is serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan, and shall continue thereafter with respect to any possible claims based on the fact that the Indemnitee was a director, officer, employee, agent, or trustee of the Company or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan. This Agreement shall be binding upon all successors and assigns of the Company (including any transferee of all or substantially all of its assets and any successor by merger or operation of law) and shall inure to the benefit of the Indemnitee's heirs, executors, and administrators.

15. Notification and Defense of Proceeding. Promptly after receipt by the Indemnitee of notice of any Proceeding, the Indemnitee shall, if a request for indemnification or an advancement of Expenses in respect thereof is to be made against the Company under this Agreement, notify the Company in writing of the commencement thereof; but the omission so to notify the Company shall not relieve it from any liability that it may have to the Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company. Notwithstanding any other provision of this Agreement, with respect to any such Proceeding of which the Indemnitee notifies the Company:

(a) The Company shall be entitled to participate therein at its own expense;

(b) Except as otherwise provided in this Section 15(b), to the extent that it may wish, the Company, jointly with any other indemnifying party similarly notified, shall be entitled to assume the defense thereof, with counsel satisfactory to the Indemnitee. After notice from the Company to the Indemnitee of its election so to assume the defense thereof, the Company shall not be liable to the Indemnitee under this Agreement for any expenses of counsel subsequently

incurred by the Indemnitee in connection with the defense thereof except as otherwise provided below. The Indemnitee shall have the right to employ the Indemnitee's own counsel in such Proceeding, but the fees and expenses of such counsel incurred after notice from the Company of its assumption of the defense thereof shall be at the expense of the Indemnitee unless (i) the employment of counsel by the Indemnitee has been authorized by the Company, (ii) the Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and the Indemnitee in the conduct of the defense of such Proceeding, or (iii) the Company shall not within 60 calendar days of receipt of notice from the Indemnitee in fact have employed counsel to assume the defense of the Proceeding, in each of which cases the fees and expenses of the Indemnitee's counsel shall be at the expense of the Company. The Company shall not be entitled to assume the defense of any Proceeding brought by or on behalf of the Company or as to which the Indemnitee shall have made the conclusion provided for in (ii) above; and

(c) Notwithstanding any other provision of this Agreement, the Company shall not be liable to indemnify the Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without the Company's written consent, or for any judicial or other award, if the Company was not given an opportunity, in accordance with this Section 15, to participate in the defense of such Proceeding. The Company shall not settle any Proceeding in any manner that would impose any penalty or limitation on or disclosure obligation with respect to the Indemnitee, or that would directly or indirectly constitute or impose any admission or acknowledgement of fault or culpability with respect to the Indemnitee, without the Indemnitee's written consent. Neither the Company nor the Indemnitee shall unreasonably withhold its consent to any proposed settlement.

16. Advancement of Expenses. All Expenses incurred by the Indemnitee in defending any Proceeding described in Sections 4 or 5 shall be paid by the Company in advance of the final disposition of such Proceeding at the request of the Indemnitee. Notwithstanding the foregoing, the Company shall not advance or continue to advance Expenses to the Indemnitee if a determination is reasonably made that the facts known at the time such determination is made demonstrate clearly and convincingly that the Indemnitee acted in bad faith or in a manner that the Indemnitee did not reasonably believe to be in or not opposed to the best interests of the Company, or, with respect to any criminal Proceeding, that the Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such determination shall be made: (i) by the Board of Directors by a majority vote of directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) by a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee. To receive an advancement of Expenses under this Agreement, the Indemnitee shall submit a written request to the Secretary of the Company. Such request shall reasonably evidence the Expenses incurred by the Indemnitee and shall include or be accompanied by an undertaking, by or on behalf of the Indemnitee, to repay all amounts so advanced if it shall ultimately be determined, by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal, that the Indemnitee is not entitled to be indemnified for such Expenses by the Company as provided by this Agreement or otherwise. The Indemnitee's undertaking to repay any such amounts is not required to be secured. Each such advancement of Expenses shall be made within 20 calendar days after the receipt by the Secretary of the Company of such written request. The Indemnitee's entitlement to Expenses under this Agreement shall include those incurred in connection with any action, suit, or proceeding by the Indemnitee seeking an adjudication pursuant to Section 11 of this Agreement (including the enforcement of this provision) to the extent the court shall determine that the Indemnitee is entitled to an advancement of Expenses hereunder.

17. Severability; Prior Indemnification Agreements. If any provision or provisions of this Agreement shall be held to be invalid, illegal, or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law (a) the validity, legality, and enforceability of such provision in any other circumstance and of the remaining provisions of this Agreement (including, without limitation, all portions of any paragraphs of this Agreement containing any such provision held to be invalid, illegal, or unenforceable, that are not by themselves invalid, illegal, or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby, and (b) to the fullest extent possible, the provisions of this Agreement (including, without limitation, all portions of any paragraph of this Agreement containing any such provision held to be invalid, illegal, or unenforceable, that are not themselves invalid, illegal, or unenforceable) shall be construed so as to give effect to the intent of the parties that the Company provide protection to the Indemnitee to the fullest enforceable extent set forth in this Agreement. This Agreement shall supersede and

replace any prior indemnification agreements entered into by and between the Company and the Indemnitee and any such prior agreements shall be terminated upon execution of this Agreement.

18. Headings; References; Pronouns. The headings of the sections of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof. References herein to section numbers are to sections of this Agreement. All pronouns and any variations thereof shall be deemed to refer to the singular or plural as appropriate.

19. Other Provisions.

(a) This Agreement and all disputes or controversies arising out of or related to this Agreement shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to the laws of any other jurisdiction that might be applied because of conflicts of laws principles of the State of Delaware, unless, if the Indemnitee is an employee of the Company, otherwise required by the law of the state in which the Indemnitee primarily resides and works.

(b) This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party.

(c) This Agreement shall not be deemed an employment contract between the Company and any Indemnitee who is an officer of the Company, and, if the Indemnitee is an officer of the Company, the Indemnitee specifically acknowledges that the Indemnitee may be discharged at any time for any reason, with or without cause, and with or without severance compensation, except as may be otherwise provided in a separate written contract between the Indemnitee and the Company.

(d) This Agreement may not be amended, modified, or supplemented in any manner, whether by course of conduct or otherwise, except by an instrument in writing specifically designated as an amendment hereto, signed on behalf of each party. No failure or delay of either party in exercising any right or remedy hereunder shall operate as a waiver thereof, and no single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such right or power, or any course of conduct, shall preclude any other or further exercise thereof or the exercise of any other right or power.

[20. Indemnification of Appointing Stockholder. If (i) OrbiMed Private Investments IX, LP and OrbiMed Genesis Master Fund, L.P. (collectively, "OrbiMed" or the "Appointing Stockholder"), which designated Indemnitee to the Board as a OrbiMed Designee pursuant to the Letter Agreement dated August 4, 2025 by and between the Company and OrbiMed, is, or is threatened to be made, a party to or a participant in any Proceeding, and (ii) the Appointing Stockholder's involvement in the Proceeding results from any claim based on the Indemnitee's service to the Company as a director or other fiduciary of the Company, the Appointing Stockholder will be entitled to indemnification hereunder for Expenses to the same extent as Indemnitee, and the terms of this Agreement as they relate to procedures for indemnification of Indemnitee and advancement of Expenses shall apply to any such indemnification of Appointing Stockholder.]

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the Company and the Indemnitee have caused this Agreement to be executed as of the date first written above.

Shattuck Labs, Inc.

By: _____
Name:
Title:

_____
_____, Indemnitee

[SIGNATURE PAGE TO INDEMNIFICATION AGREEMENT]

SHATTUCK LABS

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Non-Employee Director Compensation Policy (this "Policy") of Shattuck Labs, Inc. (the "Company"), is to provide a compensation package that enables the Company to attract and retain high-caliber directors and aligns their interests with the interests of the Company's stockholders.

1. Eligibility

The Policy applies to all members of the Company's Board of Directors (the "Board") who are not employees or officers of the Company or its subsidiaries. Directors who are employees or officers of the Company or its subsidiaries do not receive compensation for their service on the Board.

2. Cash Retainers

The Company shall pay annual cash retainers as set forth below:

Annual retainer for Board membership (other than the Chairman)	$	40,000
Annual retainer for Non-Executive Chairman of the Board (if applicable)	$	72,500
Annual retainer for Lead Independent Director (if applicable)	$	60,000
Additional annual retainers		
• Chair of the Audit Committee	$	15,000
• Chair of the Compensation Committee	$	12,000
• Chair of the Nominating and Corporate Governance Committee	$	8,000
• Member of the Audit Committee (other than Chair)	$	7,500
• Member of the Compensation Committee (other than Chair)	$	6,000
• Member of the Nominating and Corporate Governance Committee (other than Chair)	$	4,000

3. Equity Awards

The Compensation Committee of the Board shall also grant: (i) each new non-employee director an initial, one-time award of twice the number of stock options that are granted on an annual basis and that vests over a three-year period subject to such director's continued service, the grant date being as soon as practicable after the non-employee director is appointed to the Board, including, taking into account open trading windows under the Company's insider trading policy; and (ii) to each non-employee director on an annual basis, an award of 81,000 stock options that vests over a one-year period (or if sooner, immediately prior to the next annual meeting of the Company's shareholders).

4. Director Pay Limit

The total amount of cash retainers paid and equity awards (valued based on the grant date fair value) granted by the Company to any director for his or her service on the Board shall not exceed $750,000 in any fiscal year.

5. Administration

The Board, with the assistance of the Compensation Committee, administers the Policy and may amend the Policy at any time in its sole discretion.

Policy adopted on September 8, 2020

Policy last amended on February 10, 2026

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

MASTER SERVICES AGREEMENT - DEVELOPMENT AND CLINICAL MANUFACTURING PROJECTS

This Master Services Agreement is executed on this 18 November 2024 (the "**Effective Date**"), by and between:

SHATTUCK LABS, INC., a company incorporated under the laws of the State of Delaware and having an office at 500 W. 5th Street, Suite 1200, Austin, Texas 78701, USA (hereinafter referred to as the "**Client/Shattuck**", which expression, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and permitted assigns) of the **First Part**.

AND

KEMWELL BIOPHARMA PRIVATE LIMITED, a company incorporated under the provisions of the Companies Act, 2013 and having its registered office at Kemwell House, No. 11, Tumkur Road, Bangalore, 560 022 (hereinafter referred to as "**Kemwell**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) of the **Other Part**.

"**Party**" or "**Parties**" shall mean the Client or Kemwell, individually or collectively, as the context so requires.

WHEREAS:

A. The Client is engaged in the business of biopharmaceutical research and development focused on the development of pioneering novel bi-functional fusion proteins;

B. Kemwell is a contract manufacturer and engaged in the business of providing biopharmaceutical development and manufacturing services; and

C. The Client desires Kemwell to perform Services (defined below) in accordance with the terms of this Agreement, and Kemwell has agreed to perform such Services for the Client on the terms and conditions set out in this Agreement.

Now, therefore, in consideration of the above statements, which form part of this Agreement, and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1. Definitions

The capitalised terms used in this Agreement shall bear the meaning given herein below. Any capitalised terms used and not defined herein shall have the meaning ascribed to it in the Quality Agreement, as the case may be.

"**Affiliate**"	Any company, partnership or other entity which directly or indirectly through one or more intermediaries owns or controls or is owned or controlled by a Party or is under common control with a Party. For the purpose of this definition, control means the direct or indirect beneficial ownership of more than 50% of the voting share capital in such company, partnership or entity (by an agreement or by any other means) or the power to directly or indirectly control or cause the direction of the general management and policies of such company, partnership or entity or the power to directly or indirectly elect or appoint more than 50% of the members of such company, partnership or entity;
"**Agreement**"	This Master Services Agreement including all recitals, annexures, schedules or Exhibits that may be annexed to this Agreement and any amendments or supplements to the foregoing made in accordance with this Agreement, from time to time;

"**Applicable Law**"	Any law, rule, regulation, statute, ordinance, order, treaty, judgment, notification, decree, injunction, writ, by-law, Government approval, directive, guideline, requirement, notices, instructions, decisions, awards and regulations or other governmental restriction, of any Authority having jurisdiction over the relevant Party's activities under this Agreement as such are in effect as of the date hereof or as may be amended, modified, enacted or revoked from time to time hereafter;
"**Authorisation**"	Any consent, authorisation, permission, grant, no objection certificate, registrations, waivers, approval, resolution, registration, filing, agreement, notarisation, ratification, privileges, acknowledgements, certificate, license, approval, permit, authorisation or exemption from, by or with any Authority, whether given by express action or deemed given by failure to act within any specified time period and all corporate, creditors' and shareholders' approvals or consents;
"**Authority**"	Any national, supranational, regional, state or local government or governmental, administrative, fiscal, judicial, quasi-judicial or government-owned body, department, commission, authority, court, board, tribunal, agency or entity;
"**Batch**"	Shall refer to a specific quantity of a Drug Substance or Drug Product, as the case may be, that is intended to have uniform character and quality, within specified limits, and is produced according to standard manufacturing process during the same cycle of manufacture;
"**Drug Product Batch/DP Batch**"	One continuous Batch consisting of the fill and finish of a Drug Substance Batch(es);
"**Drug Substance Batch/DS Batch**"	One bioreactor run using the Cell Line at a specified bioreactor scale, and such purification, analytical and further processing steps applicable to the Drug Substance, harvested from that run as are described in the relevant SOW;
"**Business Day**"	Any day which is not (i) a Saturday, (ii) a Sunday, (iii) a day during which scheduled commercial banks are generally closed for business in Mumbai and Bengaluru, India, or the place where an act is to be performed, notice is to be received or a payment is to be made, or (iv) a day on which federally insured depository institutions in New York are authorized or obligated by law, regulation, governmental decree or executive order to be closed;
"**Cell Line**"	In respect of a given Drug Product, the cell line described in the relevant SOW, provided to Kemwell by the Client or a third party on behalf of the Client, for performing the Services and any modified strains of the Cell Line constructed in accordance with the Services and any progeny clone of the foregoing Cell Line(s);
"**Process Development**"	The method for manufacture, harvesting and purification of the Product comprising of Upstream Process and Downstream Process as described herein; "**Upstream Process**" shall mean the entire process from early cell isolation and cultivation, to cell banking and culture expansion of the cells until final harvest (termination of the culture and collection of the live cell batch); "**Downstream Process**" shall mean the bioprocess where the cell mass from the Upstream Process are processed to meet purity and quality requirements. Downstream Processing includes cell disruption, a purification section, a polishing section, analysis of final product, formulation and storage;

"**Certificate of Analysis**"	Certificate of analysis form issued by Kemwell and confirming that the Product belonging to each Batch to which the certificate relates, meets the applicable Specifications (including the results of analysis and testing of such Product), cGMP (in the case of cGMP Batches), Applicable Laws and such other criteria as identified on the certificate, in a form agreed to by the Client;
"**Certificate of Compliance**"	A document produced by the quality unit at the time of Product dispatch certifying that the Product meets the required standards in accordance with established regulations and GMP norms;
"**cGMP**"	Current good manufacturing practices required under applicable regulations and by the following regulatory authorities: FDA (including 21 CFR 210 and 211) (United States), EMA (including ICH Q7) (United Kingdom), Medical and Healthcare Products Regulatory Agency (and any successor thereof) (United Kingdom), Central Drugs Standard Control Organisation (and any successor thereof) (Indian), and any other regulatory agency specifically included in the SOW for a Product, in effect at the time in question for the manufacture and testing of pharmaceutical materials;
"**cGMP Batch**"	A batch of Products (either cGMP DP Batch or cGMP DS Batch, as the case may be) manufactured after the completion of the manufacturing of all non-cGMP Batches and validation of the Specifications and manufacturing process thereby, and which batch of Products has been designated as such in the SOW or agreed between the Parties as being a cGMP Batch;
"**Commercial Batches**"	A Batch of bulk Product units, which are manufactured together in one process under the Supply Agreement for Commercialisation purposes;
"**Commercialisation**"	All activities related to importing, storing, transporting, distributing, marketing, commercialising, promoting and selling the Product all across the world;
"**Client Materials**"	The Cell Line, cell banks, vectors, plasmids, reagents, consumables, specified equipment as provided by the Client to Kemwell as a right to use for the purpose of performing the Services under this Agreement, manuals, or instructions and all other materials which, as of the Effective Date and thereafter, are owned, developed, licensed or controlled by or on behalf of the Client relating to the development, formulation, manufacture, processing, packaging, analysis or testing of the Product;
"**Confidential Information**"	A Party's technology, formulations, processes, data, know-how, technical information and other information which is either marked as `confidential'/'private' or which by its very nature is deemed to be confidential, proprietary and/or not generally available to the public whether written or oral, technical or non-technical, including, without limitation, financial statements, reports, pricing, trade secrets, secret processes, formulas, manufacturing information, specified equipment, unannounced products and services, present and future product plans, volume estimates, product enhancement information, marketing plans, sales strategies, market testing information, development plans, specifications, customer requirements, designs, plans, apparatus, data or other technical information;
"**Deliverables**"	The data, results and materials generated from the performance of the Services including the Product;

"**Drug Product**"	The drug product as defined in each SOW executed pursuant to this Agreement
"**Drug Substance**"	The active pharmaceutical ingredient used in the applicable Drug Product
"**EMA**"	European Medicines Agency, or any successor entity thereto;
"**Exhibit**"	One or more of the Exhibits to this Agreement;
"**FDA**"	United States Food and Drug Administration, or any successor entity thereto.
"**Improvements**"	Any and all results, discoveries, improvements and/or inventions (whether or not patentable) made, developed or conceived by or on behalf of a Party;
"**Intellectual Property**"	All intellectual property, including (without limitation) (a) all inventions and discoveries, whether patentable or not, patents and patent applications, patent disclosures, utility models, utility model applications, petty patents, statutory invention registrations, certificates of invention, designs, industrial designs, concepts, creations, design registrations and applications (including all reissues, renewals, divisions, provisionals, non-provisionals, continuations, continuations-in-part, extensions, supplementary protection certificates, restorations and reexaminations thereof for any of the foregoing), registered or applied for, all improvements to the inventions disclosed in each such registration, patent or patent application and all other indicia of invention ownership by any Authority; (b) patents, trademarks, service marks, trade dress, rights of publicity, registered designs, trade names, corporate/business names, assumed names, symbols, brand names, fictitious names and product names, domain names, symbols and logos or other identifying marks, whether or not registered (and including any registrations and applications to register the foregoing) and all goodwill associated therewith; (c) copyrights (whether or not registered) and registrations and applications for registration thereof, including all derivative works, moral rights, copyrightable subject matter, original works of authorship, algorithms, design rights, and design right registrations and any and all renewals, extensions, reversions or restorations associated with such copyrights and any of the foregoing, now or hereafter provided by law, regardless of the medium of fixation or means of expression; (d) technical information and computer program codes, computer software, (including source code, object code, interpreted code, firmware, middleware, operating systems and specifications), data processing, communications, inventory management, website content, programs, program interfaces, other computer systems, manuals and design documentation relating to recipes, ingredients, inventions, tools, discoveries and trade secrets and all documentation relating to the foregoing; (e) Confidential Information, know-how (including manufacturing and production processes and techniques and research and development information), formulae, methods, processes, techniques, plans, data, flowcharts, drawings, recipes, ingredients, specifications, clinical data, characteristics, designs, inventions, test results, scientific or other notes or entries, discoveries, samples, pharmacology, methodologies, improvements, experience, and software products (including any obligations and source and object code related to such a product); (f) licenses or similar user rights in respect of any such rights and interests; (g) all proprietary information. "**Intellectual Property Rights**" means any and all rights and interests (including common law rights and interests) in, arising out of, or associated with any of the Intellectual Property in any jurisdiction throughout the world;

"**Manufacturing Documentation**"	With respect to a given Product, includes without limitation the data acquired and generated, documents and records describing or otherwise related to the manufacturing process including without limitation documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications, analytical methods, process trend and variability data; validation protocols and reports; Process Development reports; Batch records; Batch related documents and SOPs including without limitation SOPs for the raw material handling, manufacturing operations, equipment operation, in-process, final Product and stability quality control testing, quality assurance, validation, storage and shipping;
"**non-cGMP Batch**"	Any Batch of Products intended for non-clinical use and shall mean and include: (i) the development Batch, (ii) engineering Batch, (iii) toxicology Batch (manufactured as per cGLP) and other Batches as detailed in the applicable SOW.
"**Objective**"	The desired outcome of the Services as described in this Agreement and the Exhibit or SOW;
"**Price**"	The price for the Services (or any part or Stage of the Services as context requires) as defined in the applicable SOW and itemised on a Stage by Stage basis;
"**Product Capital Expenditure**"	All expenditure incurred or reimbursed (as applicable) by the Client solely towards upgradation, modifications on the Facility in order to meet the Client's Product manufacturing requirements as detailed in this Agreement. For avoidance of ambiguity, Product Capital Expenditure shall not include any Facility Capital Expenditure i.e. costs incurred by Kemwell related to in order to set-up maintain, upkeep or upgrade the Facility (including but not limited to equipment, infrastructure or quality compliances, QC laboratories thereof) valid, complaint and operational as per Applicable Laws, quality compliances including but not limited to cGMP certifications, industry standards or pursuant to this Agreement;
"**Product**"	The Drug Substance or the Drug Product, as the case may be, derived from a Batch;
"**Quality Agreement**"	The quality agreement setting out the Parties' responsibilities for quality assurance under Applicable Laws, which shall be in alignment with cGMP requirements per the FDA. The Parties shall endeavour [***] to execute the Quality Agreement within [***] of execution of this Agreement;
"**Reference Product**" or "**RP**"	The single biological product, as described in the relevant SOW, against which a proposed biosimilar Product is compared;
"**Schedule**"	The proposed schedule for the performance of the Services as set out in the SOW;
"**Services**"	Any or all parts of the services to be conducted by Kemwell as fully described in the relevant SOWs;
"**Specification**"	The specification of the Product as defined in the SOW or Quality Agreement or as otherwise agreed between the Parties;
"**Stage**"	A particular activity or series of conjoined activities that constitute a main step in the Services and which is more clearly identified in the SOW by the breakdown of the Services into numbered stages;

"**Timeline**"	The estimated timeline for the performance of the Services as set out in the SOW;
"**Vendor**"	A third-party vendor whom Kemwell appoints to provide the Services subject to prior written approval of the Client.

1.2. Where the context requires words "persons" or "entities" shall include individuals, partnerships, firms, companies, voluntary associations, joint ventures, trusts, corporations and organisations holding legal recognition.

1.3. A reference in this Agreement to any recitals, section, paragraph, annexure, exhibit or attachment is, except where it is expressly stated to the contrary, a reference to a recital, section, paragraph, annexure, exhibit or attachment of this Agreement.

1.4. Headings contained in this Agreement are for convenience of reference only, will not be deemed a part hereof or thereof, and shall not be taken into consideration in the interpretation or construction of the Agreement.

1.5. Each reference to this Agreement or to any other document, contract or agreement shall include a reference to this Agreement or such document, contract, or agreement as amended, varied, supplemented, substituted, assigned or novated from time to time.

1.6. References to any Applicable Law shall be such Applicable Laws for the time being in force and shall be construed as including any statute or statutory provision which is amended, enacted, re-enacted, consolidated, replaced or supplemented.

1.7. The words denoting singular shall include the plural and *vice versa.* Words denoting any gender shall include all genders unless the context otherwise requires.

1.8. The terms "include" and "including" shall be construed to mean, "include without limitation".

1.9. a time period for a payment to be made or an act to be done shall be calculated by excluding the day on which that period commences and including the day on which that period ends. If the last day of such period is not a Business Day, the due day for the relevant payment to be made or the act to be done shall be the next Business Day.

1.10. Whenever any payment or action under this Agreement is required to be made or taken on a day other than a Business Day, such payment shall be made, or such action shall be taken the following Business Day.

1.11. any reference to this Agreement includes the recitals, Exhibits and Annexures to it each of which forms an integral part of this Agreement for all purposes.

1.12. the terms "hereof", "herein", "hereto", "hereunder" or similar expressions used in this Agreement mean and refer to this Agreement and not to any particular clause of this Agreement.

1.13. a reference to writing includes a facsimile or electronic transmission and any means of reproducing or representing words in a tangible and permanently visible form.

2. SERVICES TO BE PERFORMED

Scope. During the Term (or, if shorter, the period set forth in the applicable SOW for one or more Services), on the terms and conditions of this Agreement, Kemwell shall perform the Services with respect to each project, as detailed in the statement of work, each such statement of work to be executed substantially in the form set out in Exhibit I ("**SOW**") and in the Quality Agreement. All project plans, protocols, reports and other approved documentation will be shared by Kemwell to the Client to be approved by the Client. Each SOW will automatically incorporate the terms and conditions of this Agreement and this Agreement together with each SOW (including any attachments or schedules thereto), but separate and apart from any other SOW and the Quality Agreement, shall constitute the entire

agreement between the Parties for the performance of any Services defined in the applicable SOW. Each SOW shall be binding on the Parties only if signed by an authorised representative of the Client and Kemwell. The Services shall be performed in accordance with Applicable Laws, in compliance with the Quality Agreement and in the manner contemplated in this Agreement. Kemwell shall maintain the premises where its Services are performed ("**Facility**") in accordance with cGMP and Applicable Laws and in such conditions as will allow Kemwell to perform the Services in accordance with the terms of this Agreement, the Quality Agreement, the SOWs and Applicable Laws. In the event that the Client requests Kemwell, in writing with reasonable notice, to perform additional services beyond the scope of Services specifically stated in the SOW, a Change Order will be executed in accordance with Section 6 below provided that the prices for the additional services shall be discussed and agreed between the Parties in writing. For the avoidance of doubt, the services provided thereunder shall be in addition to the Services and shall be invoiced separately. The Parties shall amend or supplement any SOW, as applicable, to reflect such modification or addition, and any such modification or addition will be deemed to be a "Service" under this Agreement with effect from the date of such amendment or supplement, or such later date as the Parties may agree in writing.

2.1A All Client Material will be listed, identified and segregated to the extent possible and during the Term and the ownership of such Client material shall remain with the Client. All Client Material shall be solely used for the purpose of this Agreement to manufacture the Product for the Client. However, if Kemwell would like to use the Client Material for any other use, Kemwell will take prior approval of the Client (which consent [***]) and both Parties will mutually discuss and agree on the terms of use and payment terms. Kemwell shall not alienate or encumber or create any charge or lien on such asset in any manner at any time and shall act as an involuntary bailee for such Client Material. Upon termination or expiration of this Agreement, Kemwell shall, at the expense of [***], transfer such Client Material to Client within timelines as [***] required by Client. For the avoidance of doubt, any cost incurred by Kemwell for transfer of the Client Materials shall be solely at the expense of [***].

2.1. Compliance with Manufacturing Instructions. All Services shall be performed by Kemwell in compliance with the manufacturing instructions, as provided by the Client. This shall not limit Kemwell from performing the Services in a manner outside the scope of the manufacturing instructions, provided prior written approval is obtained from the Client. All manufacturing instructions pertaining to any Services shall be provided by the Client not less than [***] prior to the commencement of such Services. Any changes or revisions to the manufacturing instructions pertaining to any Services after the aforesaid period shall be subject to review and agreement on implementation by Kemwell, and any costs of such implementation shall be, subject to prior written consent of the Client, and shall be additionally borne by [***].

2.2. Delivery of Service and Products. Subject to the Client's delivery to Kemwell of the relevant Cell Line (in appropriate and agreed quantities), Kemwell shall deliver to the Client the Products and Services within the Timeline. Unless specifically agreed otherwise and recorded in writing, all deliveries of Deliverables and Products will be delivered to Company on DDP (Delivery Duty Paid) basis as per Incoterms 2020 (subject to qualifications set out in this Agreement) at the location specified in the applicable SOW. Kemwell will insure each shipment for the benefit of Client. The insurance policy terms shall be provided by Kemwell to the Client for mutual agreement in advance of any shipment. [***]. It is mutually agreed that freight and insurance costs relating to the delivery of Deliverables and Products shall be initially borne by Kemwell, which cost shall be negotiated and pre-agreed by Client and reimbursed [***] by the Client. In addition to such reimbursement [***], the Client further agrees to pay Kemwell a handling fee equivalent to [***], which shall cover Kemwell's administrative and operational costs associated with arranging the insurance coverage for the shipments. All Deliverables and Products delivered hereunder will be suitably packed and shipped by Kemwell in accordance with good commercial practice and, where applicable, GMP. The Client shall be responsible for obtaining any import license, documentation or other official authorisation and carrying out any other customs formalities necessary for the importation of the Deliverables and Products to the delivery location specified by the Client.

2.3. Specifications. Unless agreed otherwise in writing, each cGMP Batch manufactured by Kemwell shall meet the Specification outlined in the respective protocol, cGMP and Applicable Laws, and in the case of cGMP Batches, shall be in conformance with the definitions provided

under the FDA's Code of Federal Regulations 21 CFR 210.3 and European Medicines Agency's EMA ICH Q7. Client shall provide the Specification to Kemwell for development of the Batch documentation, which Specification may be amended by mutual agreement between the Client and Kemwell, provided that the revised Specification is set out in writing. Any agreed revised Specifications shall come into effect on any batches of Products which are due for manufacture after [***] from the date of agreement on the revised Specifications, unless otherwise agreed between the Parties in writing.

2.4. Conformance. Client will notify Kemwell in writing of its acceptance or rejection of each Batch within [***] of receipt of the complete Batch records relating to such Batch. Client may reject a Batch if such Batch is contaminated, does not conform with the Specifications, or does not comply with Applicable Laws or the Quality Agreement, or was not manufactured pursuant to the applicable manufacturing process approved by Client (such Batch has a "Defect" and is "**Defective**"). The Parties hereby agree that Kemwell shall only be liable for the Defect in the following circumstances: (i) [***]; and (ii) [***]. If there is a disagreement between the Parties as to whether any Batch is Defective and that Kemwell is liable for such Defect as per the provisions of this Clause 2.4, the quality assurance representatives of the Parties will discuss [***] to attempt to resolve any such disagreement. If the Parties disagree on whether a Batch is a Defective or the reason a Batch does not conform to the Specifications and that Kemwell is liable for such defect as per the provisions of this Clause 2.4, the dispute shall be referred to a mutually agreed internationally reputed and competent testing laboratory, such laboratory being an independent technical expert. The independent technical expert's decision shall be binding on the Parties. If such expert finds that the Batch in question is Defective and that Kemwell is liable for such defect as per the terms set forth in this Clause 2.4, then Kemwell shall bear the fees and expenses of the testing. If such expert finds that the Batch in question is not Defective or the Defect is not attributable to Kemwell's fault or Kemwell is not liable for such Defect as stated hereinabove, then the Client shall bear the fees and expenses of the testing. The Parties undertake to give the independent expert a maximum of [***] to carry out its task.

2.5. Remedy.For a Defective Batch attributable to Kemwell as above, Kemwell will replace such Defective Batch or Deliverable within [***]. It is clarified that any finding of a Defect shall not absolve or allow for delay in the completion of payments of Fees due for such Batch upon successful completion of the replacement Batch, as the Client acknowledges that it is being provided with an efficacious remedy as set out above to address the rejection of a Batch found to be Defective. The Parties hereby agree that, in the event the Defect arises as a direct result of Kemwell's willful misconduct or gross negligence, Kemwell shall [***]. However, if the Batch is found to be Defective (and which Defect is attributable to Kemwell as above) for reasons other than gross negligence or willful misconduct on the part of Kemwell, then Kemwell's responsibility shall be limited to [***].

2.6. Certificate of Analysis. The Certificate of Analysis and all other documents will be delivered to the Client for each Batch.

2.7. Timeline. Subject to the provisions of this Agreement Kemwell shall perform the Services in accordance with the Timelines outlined under the applicable SOW, time being the essence of the Agreement and the SOW. The Timeline may be amended by mutual agreement between the Client and Kemwell, provided that the revised Timeline is set out in writing. Kemwell shall provide the Services in accordance with the Timelines set out in the relevant SOW, [***]. In the event of delay attributable solely to Kemwell and connected to the Services to be provided, the Parties shall [***], post completion of the relevant timeline, discuss and agree on remedial steps to resolve the issues and reasons causing the delay.

2.8. Kemwell shall not sub-contract any portion of the Services without the prior written consent of the Client; provided, however, in the event that the Client provides its consent, Kemwell shall at all times be liable and responsible for such approved sub-contractors.

3. PERFORMANCE

3.1. Project Manager. On a project-by-project basis, each Party shall appoint a project manager. The project managers will work together to ensure the satisfactory execution of the Services in accordance with the terms of this Agreement. Each project manager shall be entitled to propose recommendations to the Parties to ensure that the project meets its Objectives. A Party may replace its project manager with notice to the other Party of such replacement within a period of [***] from date of such replacement. Each Party shall cause its employees to cooperate reasonably with the employees of the other to the extent required for the efficient provision of the Services.

3.1A Meetings:

(a) During the Term, the Client shall sponsor, and the project managers appointed by the Parties shall convene and hold such meetings as provided hereinbelow, by providing reasonable notice to the Parties prior to such meetings. All such meetings shall be attended by the subject matter experts ("**SMEs**") designated by the Client for this purpose and such other members on an as-needed basis.

(b) CMC *Meeting.* The Parties shall, on a weekly or on an as-needed basis, convene meetings for the purpose of receiving updates on functional areas with respect to the Project, addressing operational issues in relation to Chemistry, Manufacturing and Controls ("**CMC**") matters and other such purposes as the Client may communicate from time to time. The CMC meetings shall be attended by SMEs from all functional areas including quality, regulatory and supply chain sectors to (i) receive an update / track progress, (ii) supervise the work performed by Kemwell and/or a sub-contracter appointed by Kemwell in accordance with the terms of the Agreement; (iii) advise if there are any changes that need to be undertaken; and (iv) for such other purposes as the Client may decide from time to time.

(c) *Technical Meeting*. The Parties shall, on a bi-weekly or on an as-needed basis, convene meetings for the purpose of discussing and addressing scientific and technical issues related to the project.

3.2. Schedule. The project manager of Kemwell, in consultation with the project manager of the Client, shall report to the Client in accordance with the Timeline set for the performance of the Services in the Gantt charts (as previously agreed to and outlined in the relevant SOW) on a weekly basis, and if required, provide daily updates.

3.3. Technical Difficulties. If it becomes apparent to either Kemwell or the Client at any Stage in the provision of any Services that, as a result of scientific or technical reasons out of the reasonable control of either Party ("**Technical Difficulties**"), it will not be possible to complete the Services in the manner described in this Agreement or in SOW(s) or any Change Order thereto, the relevant Party will (a) identify the problem and notify the other Party in writing within [***], (b) submit the problem in writing to senior management of each Party, and (c) negotiate [***] for a [***] period regarding how to resolve such problem in a [***] manner. If the Parties do not agree on a reasonable resolution to the problems within such [***] period, neither Party shall be liable for any failure to perform any of their respective obligations under this Agreement if the performance is prevented, hindered or delayed by such Technical Difficulties, and the issue shall be [***] referred to the Client and, based on the discussion between Kemwell and Client, the Client may suspend either Parties' obligations under the Agreement for so long as the Technical Difficulties are not resolved in the manner contemplated in this Agreement.

3.4. **Product Capital Expenditure**

(a) Subject to prior written approval from the Client on Product Capital Expenditures which shall include equipment details, related specifications details and rates of such equipment, Kemwell shall install the required equipment for manufacturing, supporting infrastructure ("**Specific Assets**") as deemed fit by the Client for manufacturing of the Product. The Client agrees to reimburse Kemwell for [***].

(b) For any additional Product Capital Expenditure beyond the procurement of the equipment detailed in this Agreement and not related to Facility Capital Expenditure, the Parties agree that, [***], the Client may (i) procure such equipment for Kemwell and provide the same to Kemwell for installation at the Facility and usage for the manufacturing of the Product; or (ii) allow Kemwell to procure such equipment, with prior written approval of Client on the equipment details, related specifications details, Vendors, rates and payment terms of such equipment, before any such costs are incurred by Kemwell.

(c) In each instance of Kemwell incurring additional Product Capital Expenditure, the Client shall pay Kemwell [***], and which payment shall be made by the Client as per payment terms of such Vendors. Any equipment or facilities or machines or supporting infrastructure procured pursuant to such additional Product Capital Expenditure as per Section 3.4(b) shall also be construed as integral part of the Specific Assets along with equipment for manufacturing, supporting infrastructure

provided by Client under Section 3.4(a). In case of any change in make or nature of equipment intended to be procured by Kemwell after the receipt of approval for such purchase from the Client, Kemwell shall re-obtain approval from the Client for the revised equipment prior to making any purchase of such equipment.

(d) All Specific Assets will be listed, identified and segregated to the extent possible and during the Term and the ownership of such Specific Assets shall remain with the Client. All Specific Assets shall be solely used for the purpose of this Agreement to manufacture the Product for the Client. However, if Kemwell would like to use the Specific Assets for any other use, Kemwell will take prior approval of the Client and both Parties will mutually discuss and agree on the terms of use and payment terms. Kemwell shall not alienate or encumber or create any charge or lien on such asset in any manner at any time and shall act as an involuntary bailee for such Specific Assets. Upon termination or expiration of this Agreement, Kemwell shall at the expense of [***], disassemble, pack and, transfer such Specific Assets to Client within timelines as reasonably required by Client.

(e) Any expenditure towards maintenance of the Facility as per cGMP standards, including replacement of Kemwell equipment and other items necessary to ensure reliable functioning including preventive maintenance according to regulatory guidelines and commercially reasonable industry practices, will be at Kemwell's costs and not charged to the Client. The Client shall be responsible for the maintenance cost of the Specific Assets in accordance with recommended specifications of the relevant manufacturer, insurance costs as agreed for the Specific Assets, and for the cost of repairing or replacing Specific Assets found to be deficient or affected by wear and tear to the extent that good industry practice requires such Specific Asset(s) to be replaced, provided that such replacement is not on account of any wilful misconduct or usage of Specific Assets in violation of recommended usage parameters attached to such Specific Assets.

4. INSPECTIONS, RECORDS AND AUDITS

4.1. Regulatory Inspections. Kemwell will notify the Client within [***] after being notified of and at least [***] in advance of any inspections by any Authorities directly relating to the Services with respect to the Product in accordance with the terms of the Quality Agreement, and the Client and its representatives (including its quality person) shall be permitted to remain present at such inspections and participate in those portions of such inspection where Product related topics will be discussed. Kemwell will also provide a summary of any findings and resulting actions needed to the Client within [***] of any inspection or finding related to a manufacturing process that is also part of the process for Client's Product. The Client shall be provided copies of Kemwell's responses to the Authority inquiries prior to submission to the Authority and with sufficient time to allow review and comment by the Client. Kemwell shall take prompt steps to address, in consultation with the Client, and correct any concerns raised by such inspections. Kemwell agrees to cooperate with all such Authorities and submit to the inspections by such Authorities. Kemwell further undertakes to furnish to the Client a complete copy of the inspection reports relating to the Services with respect to the Products, if so shared by the Authorities. Upon written request by the Client, Kemwell will also share a summary report *(e.g.,* FDA Form 483, or equivalent) of any other inspections within [***] of such written request provided information of other customers shall be redacted and be kept confidential. Further, in the event Kemwell receives any notice of observations, warning letter or other written communication from an Authority, Kemwell shall notify the Client in writing within [***] and shall supply the Client and its representatives with copies of any relevant correspondence, notices and other relevant documentation related to the same.

4.2. Client Audit/Inspections. The Client shall have the right to audit such sections of the Facility and documents utilised for rendering the Services with respect to the Product during normal operating hours upon prior written notice of [***] given to Kemwell; provided, however, that in the event that the Client is made aware of or has a reasonable cause to suspect any issue (including any quality or technical difficulties) with respect to the Services, Kemwell shall provide access earlier to the Facility for the purpose of investigating or addressing such issues. The number of audits shall be limited to [***] in each successive year from the Effective Date (if not for cause, required by Applicable Law or otherwise requested by any Authority), unless there is any discrepancy discovered during the audit, in which case, the Client shall be permitted to audit the Facility once more to ascertain whether such discrepancy has been rectified by Kemwell. Kemwell agrees to give the Client and its representatives all reasonable access to the manufacturing, warehousing, packaging and laboratory areas and all other areas as are related to the Product and the Services with

respect to the Products. Reasonable access to documentation and reference materials shall be granted to the Client during such audit. In addition to such audit, the Client shall have the right to request documents on a routine basis from Kemwell in connection with the performance of the Services with respect to the Products from time to time. Kemwell agrees to [***] remedy any non-compliance, deviations, deficiencies and/or failures caused by and/or within the control of Kemwell discovered during such audit at no additional charge to the Client. The Client will be permitted to have its representatives to be on-site at the Facility to observe and consult with Kemwell during the performance of Services with respect to the Products under this Agreement and the SOW.

4.3. Report. Without limiting any obligations of Kemwell to deliver to the Client all documentation and reports under an SOW, Kemwell agrees to provide to the Client with a report, which report shall be subject to Client's approval, upon completion or termination of the applicable Services pursuant to such SOW, describing in detail the procedures and results obtained in accordance with synthesising, analysing, developing, testing and/or manufacturing the applicable Product(s), including without limitation, applicable manufacturing process(es), and all Intellectual Property. Kemwell acknowledges and agrees to revise the report in accordance with the instructions communicated by the Client from time to time. Each such report will contain sufficient detail so that the Client can understand and fully implement and exploit on its own the information described therein, including such information as is required for the CMC section of the investigational new drug (IND) or biological license application (BLA) for such Product and the master Batch record. Upon request by the Client from time to time, Kemwell will provide all assistance to the Client to understand and implement the information contained in any such report.

4.4. Record Retention. Kemwell will retain copies of all Batch documentation and all other records or documentation it generates in connection with the Services, and all records that may be reasonably necessary to assist Client with regulatory requirements or in the event of a Product stock recovery, recall, adverse drug event, or complaint, in accordance with Applicable Laws for investigational drug products used in clinical trials globally, Kemwell's standard operating procedures, and the timelines set forth in the Quality Agreement. Such records and documentation shall properly reflect the work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

4.5. Manufacturing Documentation. Kemwell agrees and acknowledges that notwithstanding anything contained herein, the Manufacturing Documentation shall be the sole and absolute property of the Client and all rights, title and interest, including Intellectual Property Rights, in the Manufacturing Documentation shall absolutely and exclusively belong to the Client. All Manufacturing Documentation for cGMP Batches shall be generated and maintained by Kemwell in accordance with cGMP. Kemwell shall maintain the Manufacturing Documentation to be true and accurate and shall keep in strict confidence and shall not use for the purpose other than providing or performing the Services or other obligations hereunder.

5. COMPENSATION

5.1. Fees and Invoices. In consideration for Kemwell performing the Services in accordance with the terms and conditions of this Agreement and the applicable SOW, the Client shall pay to Kemwell pursuant to the payment milestones outlines in the applicable SOW. For avoidance of doubt, the expenses incurred by Kemwell in procuring any material or third-party services in performing the Services shall be reimbursed by the Client to Kemwell [***] (collectively the "**Service Fee**"). In accordance with the terms of the SOW, Kemwell shall provide to the Client invoices of the applicable Service Fee on a [***] basis or as agreed to in the relevant SOW (each, an "**Invoice**"), and each Invoice shall include the relevant SOW reference, the purchase order number (which Client shall provide to Kemwell) and associated line item numbers, a detailed description of the Services performed, and the total amount due for such Services. Kemwell shall e-mail the Invoice to [***] with a copy to applicable Client personnel as directed by Client. The Client shall pay each undisputed Invoice within [***] from the date of receipt of an Invoice for Service Fee and [***] from the date of receipt of an Invoice/pro forma invoice for aforesaid cost of the material, by wire transfer to into the bank account of Kemwell (indicated to the Client in writing), except for the portion of any Invoice that the Client disputes by written notice to Kemwell, together with a description of the basis for the dispute. It is agreed between the Parties that any dispute with respect to the Invoice shall be raised by the Client within [***] from the date of receipt of the relevant Invoice, failing which the relevant Invoice will be deemed accepted by the Client. On the disputed amounts, Kemwell shall furnish to the Client reasonable documentation requested by the Client in this regard and thereafter the amount determined pursuant to the resolution of the dispute shall be payable by the Client within [***] from the disputed being resolved. Upon delivery of such documentation,

the Parties shall cooperate and use their reasonable efforts to resolve such dispute, failing which the dispute will be resolved in accordance with Section 18.2 of this Agreement. If payment is not received on or before the due date, Kemwell will charge [***] from the date on which payment is due until such time that the payment is received. Kemwell shall, upon request by Client, provide the Client with quarterly financial reporting information in relation to the Services, including the amount of any unbilled materials utilised for the Services and other information as may be reasonably requested by the Client.

5.2. The Client agrees to pay to Kemwell the cost of the Cell Lines and Specific Assets purchased and maintained by Kemwell for the Services after obtaining prior written consent of the Client and as may be provided in the SOW. The Client agrees to pay the entire cost of the Cell Lines and Specific Assets at [***] as per the Invoice submitted by Kemwell, subject to submission of supporting documentation.

6. CHANGE ORDERS

In the event a modification is requested by the Client, Kemwell shall provide the Client with a "Change Order" containing an estimate of the required modifications to the budget, activities and/or duration specified in the SOW ("**Change Order**"). The Client and Kemwell shall negotiate in good faith for a period of [***], following receipt of such Change Order by the Client to agree on a Change Order that is mutually acceptable. If practicable, and agreed to by the Client, Kemwell shall continue work on the Services during any such negotiations, but shall commence work with respect to any Change Order only upon written authorisation by the Client.

7. WARRANTIES

7.1. General Warranties

As of the Effective Date, each Party hereby represents and warrants to the other Party as follows:

(a) it is duly incorporated and validly existing under the laws of the county of its incorporation;

(b) it has all requisite corporate or other organisational power and authority to enter into and perform all of its obligations under this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorised by all necessary corporate action;

(c) this Agreement has been duly executed and delivered by the Party, and constitutes legal, valid and binding obligations of the Party enforceable in accordance with its terms;

(d) the execution, delivery and performance of this Agreement, will not (i) violate or conflict with any provision of its constitutional documents, (ii) violate or conflict with any Applicable Law or Authorisations applicable to the Party, or (iii) constitute a breach of or under any contract, agreement, arrangement or judgement to which the Party is a party to;

(e) to the knowledge of the Party, except as disclosed in writing, there is no proceeding or litigation by any person pending or threatened against the Party that would be reasonably likely to result in monetary damages, injunctive relief or the taking of any other action that would be reasonably expected to (in any of the foregoing cases) materially impair the ability of the Party to perform its obligations under this Agreement; and

(f) it does not require (i) to obtain any Authorisations, or waiver, of, (ii) to make any filing or registration with, or (iii) to give any notice to, any Authority in connection with or as a condition to the execution, delivery and performance of this Agreement. Notwithstanding the foregoing, it is agreed between the Parties that any Authorisations necessary under this Agreement, including for the Product, Client and Kemwell shall reasonably cooperate with each other in obtaining the same.

7.2. In addition to the representations and warranties in Section 7.1, the Client represents and warrants to Kemwell as follows:

(a) the Client Materials are free of any lien, encumbrance or charge of any kind of third parties except for permitted encumbrances;

(b) the Client is the lawful owner or, or has adequate rights and Authorisations to license and allow Kemwell to use the Client Materials to provide the Services, and to the best of the Client's knowledge (subject to reasonable due diligence), the use, by Kemwell, of Client Materials or Product(s) that Client instructs Kemwell to use in accordance with the terms of this Agreement do not infringe any valid and enforceable third-party Intellectual Property Rights; and

(c) Neither it nor any of its employees, officers or directors ("**Client Personnel**") have been debarred or is under consideration for debarment, by the FDA or any other Regulatory Authority from working in or providing any services to any pharmaceutical or biotechnology company and the Client will not use any Client Personnel who has been debarred from working in or providing any services to any pharmaceutical or biotechnology company. The Client shall [***] notify Kemwell in writing if any such proceedings have commenced or if the Client or any of its Client Personnel or subcontractors are debarred by the FDA or any other Regulatory Authority.

7.3. In addition to the representations and warranties in Section 7.1, Kemwell represents and warrants to the Client as follows:

(a) Kemwell shall perform the Services diligently in accordance with the Quality Agreement, SOW, Specifications, GMP, the Applicable Laws, the terms and conditions of this Agreement as well as the standards explicitly defined in the SOW, and pursuant to good industry standards which shall in no event be less than the efforts put in by a service provider engaged in the business of providing services same or similar to the Services to be performed herein including specifications, guidelines and requirements of the applicable Governmental Authorities pertaining to development of biosimilar products;

(b) the general technical processes based on Kemwell Pre-Existing IPR (defined below), which are applied by Kemwell when performing the Services, will not infringe upon the Intellectual Property of any third parties;

(c) Kemwell is the lawful owner of, or has adequate rights to the Facility, equipment, machinery and has all the necessary Authorisations and permissions required to enable Kemwell to perform its obligations (including providing Services) under this Agreement and the SOW and, to the best of Kemwell's knowledge, (subject to reasonable due diligence) none of Kemwell Pre-Existing IPR infringes any valid and enforceable third-party Intellectual Property Rights;

(d) at each stage of the project as mentioned under the SOW, Kemwell shall provide detailed information including but not limited to process, process conditions, reagents, composition, characterisation to be provided for evaluation by the Client with a reasonable timeline to respond;

(e) the Facility where the Services are to be provided is adequately equipped with equipment, space and infrastructure to provide the Services, excluding Specific Assets;

(f) the Deliverables and Products will be free and clear of all liens, encumbrances, security interests and other claims when delivered to the Client; and

(g) Neither it nor any of its employees, officers or directors ("**Kemwell Personnel**") have been debarred or is under consideration for debarment, by the FDA or any other Regulatory Authority from working in or providing any services to any pharmaceutical or biotechnology company and Kemwell will not use any Kemwell Personnel who has been debarred from performing the Services for the Client. Kemwell shall [***] notify the Client in writing if any such proceedings have commenced or if Kemwell or any of its Kemwell Personnel or subcontractors are debarred by the FDA or any other Regulatory Authority.

7.4. Except as expressly warranted in Section 7 of this Agreement, neither Party makes any representations or warranties, express or implied, in any manner and either in fact or by operation of law, and specifically disclaims any and all implied warranties.

7.5. Experimental Nature of Services

The Client acknowledges that the activities as outlined in the SOW or this Agreement to be undertaken by Kemwell of the Process Development phase is experimental in nature and that no favourable or useful result can be assured by Kemwell. Accordingly, and provided that Kemwell provides Services in a diligent manner and compliant with highest industry standards and industry best practices, Kemwell shall not be responsible or liable, and the Client shall not deduct, set-off or withhold payment of any Fees or otherwise render Kemwell responsible or liable in case no favourable or useful result arises from the provision of Services.

8. CONFIDENTIALITY

8.1. Each Party shall hold and treat all Confidential Information disclosed by or on behalf of the other Party in the strictest confidence and shall not publish or disclose such Confidential Information to any third party, and shall not use such Confidential Information for any purposes other than the proper performance of its obligations pursuant to this Agreement.

8.2. The receiving Party shall permit access to the disclosing Party's Confidential Information only to those of its Affiliates and its and their directors, officers, employees and representatives (hereinafter referred to as the "**Personnel**") with a need to know and who are bound by confidentiality and non-use obligations similar to those included herein. The receiving Party shall be liable for any breach of the confidentiality and non-use obligations contained herein by any of its Personnel.

8.3. The confidentiality and non-use obligations contained herein shall not apply to any Confidential Information to the extent that the same, as demonstrated by the receiving Party:

(a) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(b) becomes generally available to the public or otherwise part of the public domain after its disclosure to the receiving Party other than through any act or omission on the part of the receiving Party or its Personnel;

(c) is rightfully obtained by the receiving Party from third parties authorised to make such disclosure without restriction;

(d) was lawfully in the receiving Party's possession free of any obligation of confidentiality at the time of its disclosure to the receiving Party;

(e) was independently developed by or on behalf of the receiving Party without use of the disclosing Party's Confidential Information.

8.4. In the event the receiving Party is compelled by government, administrative, regulatory or judicial process to disclose any of the Confidential Information, the receiving Party will, to the extent legally permissible, provide prompt prior written notice thereof to the disclosing Party to enable disclosing Party to seek protective order, and the receiving Party shall disclose only the minimum of Confidential Information necessary to comply with the government, administrative, regulatory or judicial process and shall take all reasonable and lawful actions to obtain confidential treatment for such disclosure.

8.5. The confidentiality and non-use obligations contained herein shall survive the termination or expiration of this Agreement for a period of [***] from the date of such termination or expiration.

8.6. Injunctive Relief: The Parties agrees that any threatened or actual breach of any of the terms of this Agreement including the Confidential Information obligation by one Party, may cause irreparable loss to the other Party and the said loss may not be compensated by monetary compensation and, in addition to all other rights and remedies that the affected Party may have under law and equity, such affected Party will have the right to seek appropriate

injunctive relief and/or specific performance of the defaulting Party's obligations from courts of competent jurisdiction.

9. INVENTIONS, MATERIAL, PUBLICATIONS, USE OF NAME AND INTELLECTUAL PROPERTY

9.1. Inventions. The Client shall solely own and control the formulation of the Product *(i.e.,* Drug Substance and Drug Product), the Process Development and all Intellectual Property and Improvements thereto including but not limited to clinical data, ideas, information, developments, formulations, inventions, know-how, manufacturing and analytical methods and processes, enhancements and modifications to the Client Materials or Process Development, developed or conceived as a result of performing the Services under this Agreement by Kemwell's employees, agents, consultants, subcontractors or other representatives, either solely or jointly with the employees, agents, consultants and other representatives of the Client and its contractors and in connection with the Product, but expressly excluding Kemwell's Pre-Existing IPR and Kemwell Inventions, respectively (such Intellectual Property referred to as the "**Client Inventions**"). During the term of the Agreement, Kemwell will keep the Client periodically informed of the development and/or creation of the Client Inventions. Kemwell shall [***] provide to the Client any necessary information regarding each Product including any changes made to the Drug Product or Drug substance within [***], so as to conduct appropriate evaluation on a periodic basis. Kemwell will assign and hereby assigns to the Client all such Client Inventions discovered or conceived by or on behalf of Kemwell, on a perpetual and worldwide basis. Kemwell represents and warrants to the Client that it shall procure and ensure that each employee, agent, consultant and subcontractor of Kemwell is obligated to assign all of his/her/its right, title and interest in and to the Client Inventions to the Client on a perpetual and worldwide basis. Kemwell and all its employees, agents, consultants and subcontractors shall sign and deliver to the Client all writings and do all such lawful things as mat be necessary or appropriate to vest in the Client all right, title and interest in and to such Client Inventions. Kemwell expressly agrees, undertakes and covenants that neither Kemwell, nor its Affiliates, employees, agents, consultants and subcontractors have or shall have any right or claim over or in or to the Client's Intellectual Property Rights and Client Inventions and all amendments, alterations, enhancements, innovations and improvements made thereto. Kemwell undertakes and warrants that it will not reverse engineer, dissemble the information or make any variant out of the Client Inventions or the Client's Intellectual Property Rights. The Client may file for patent protection on any and all of the Client Inventions in accordance with this Section 9. Kemwell will execute any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain letters of patent of the US or of any other country with respect to the Client Inventions. For the Client Inventions assigned pursuant to this Section, the Client shall provide Kemwell a limited royalty-free, non-assignable, non-sub-licensable, non-exclusive license to use such the Client Inventions to the extent necessary to perform the Services of the Client during the Term of this Agreement. Client will, [***], have sole control of filing and prosecuting applications for, and maintenance and enforcement of, patents for Client Invention. Client shall have the sole right to prosecute, defend and/or control any litigation related to the Client Invention and/or the Product. Kemwell shall, at [***], assist Client to obtain, maintain, enforce the patents and in any litigations relating to the Client Invention and/or Product, including executing any assignments and other necessary documentation.

9.2. Kemwell Inventions. Kemwell shall own any: (a) mechanical and technical trouble-shooting knowhow generally arising in the provision of the Services and carried out solely by Kemwell on non-Client Material, not being in the nature of Improvements to the Process Development, or (b) Improvements to Kemwell's Pre-Existing IPR arising out of the provision of Services (for avoidance of doubt, this shall not include any Improvements made to Process Development) (each, a "**Kemwell Invention**"). Kemwell shall disclose to the Client in writing the list of the Kemwell Invention in writing to the Client. Kemwell shall retain sole ownership of such Kemwell Invention, and the Client shall not claim any right or interest in the same. The Parties further agree that Kemwell shall retain sole ownership and control over Kemwell Pre-Existing IPR, and the Client shall not claim any right or interest in the same, notwithstanding that such Kemwell Pre-Existing IPR is employed to provide or perform Services. Nothing contained in this Agreement shall operate to grant, convey, assign or transfer to the Client any right, or interest in or to a Kemwell Invention or Kemwell's Pre-Existing IPR.

9.3. Client Materials.

All the Client Materials that Kemwell may have access to in order to perform the Services shall be owned exclusively by the Client. Nothing in this Agreement shall be deemed to grant

any rights to Kemwell in any the Client Materials, other than the right for Kemwell to use such the Client Materials to perform the Services for the Client. All Deliverables and the Client Inventions arising out of such Services shall be owned solely and exclusively by the Client.

9.4. Publicity

Kemwell and the Client agree not to use and shall ensure that its related persons do not use, each other's or the other's Affiliates' name without prior written consent of the other Party, except where required to do so by law or by the applicable regulations or guidelines of any regulatory agency of competent jurisdiction or any stock exchange, in which case a copy of the notification shall be provided to the other Party.

9.5. Intellectual Property

(a) Pre-Existing Intellectual Property

Any Intellectual Property owned, used, acquired or held for use by a Party or licensed from a third party as of the Effective Date ("**Pre-Existing IPR**") shall remain the sole and absolute property of the Party that owned or was licensed to use such Pre-Existing IPR. Nothing in this Agreement shall act as any assignment of the Pre-Existing IPR. The Pre-Existing IPR shall not be licensed to the other Party under this Agreement, unless an express license is granted hereunder. Kemwell shall disclose to the Client in writing a list of the Pre-Existing IPR of Kemwell (or its Affiliates') in connection with the performance of the Services under this Agreement before the implementation of such Pre-Existing IPR.

(b) Client's Grant of Intellectual Property License for the Services

The Client hereby grants to Kemwell for the Term of this Agreement a non-exclusive, royalty-free, non-sub-licensable, non-assignable, limited license in respect of the Client's Pre-Existing IPR solely to the extent the same is required and necessary for the proper performance of the Services.

9.6. Prosecution

(a) Pre-Existing IPR. Kemwell will have the sole responsibility to prosecute and maintain the Kemwell Pre-Existing IPR at Kemwell's sole expense and shall ensure that the Kemwell Pre-Existing IPR is in good standing. In case Kemwell wishes to discontinue or abandon any of its Pre-Existing IPR, Kemwell shall inform to the Client in writing of such intent, and Client shall have the right to continue the prosecution of the Kemwell Pre-Existing IPR employed under the Services of the Agreement and Kemwell shall assign such Pre-Existing IPR to the Client. In such case, Kemwell shall cooperate with the Client in the course of the prosecution of such Pre Existing IPR. Kemwell shall bear all of the risk, costs and expenses (such as, but not limited to, reasonable attorney's fees and royalties for a license of a third-party patent necessarily to be acquired) of any prosecution for patent infringement or other Intellectual Property Right infringement relating to the Kemwell Pre-Existing IPR.

(b) The Client shall have the sole right and discretion to file, prosecute and maintain patent applications and patents for the Client Invention at Client's sole expense, including the selection of legal counsel. Kemwell agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of Client Invention and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the Client to apply for and to prosecute patent applications in any country.

10. INDEMNIFICATION

10.1. Indemnification by Kemwell

Kemwell shall indemnify, defend and hold harmless the Client, its Affiliates and its and their respective directors, employees, agents and officers (each, a "**Client Indemnitee**") from and against all costs, losses, judgments, awards, settlements, fines, charges, penalties, liabilities, expenses (including reasonable attorneys' fees) (collectively, "**Losses**") resulting from all lawsuits, claims, demands, actions and other proceedings by or on behalf of any third party (collectively, "**Claims**") to the extent arising out of or resulting from: (a) Kemwell's breach of its covenants, undertakings, representations and warranties under this Agreement or any of the terms of this Agreement; or (b) Kemwell's or its officers, employees, directors, agents, subcontractors or Vendors' gross negligence or intentional misconduct or fraud; (c) a violation of any Applicable Law; or (d) the use of Kemwell Pre-Existing IP or wrong deployment and use of the Cell Line for purposes other than as authorised under this Agreement, except, in each case, to the extent such Claims or Losses arise from gross negligence or intentional misconduct or fraud on the part of a Client Indemnitee or a breach of this Agreement by the Client.

10.2. Indemnification by Client

The Client shall indemnify, defend and hold harmless Kemwell, its Affiliates and its and their respective directors, employees, agents and officers (each, a "**Kemwell Indemnitee**") from and against all Losses resulting from all Claims to the extent arising out of or resulting from: (a) the Client's breach of any covenants, representations and warranties under this Agreement, (b) Kemwell's use of the Client Material in accordance with this Agreement, (c) any infringement of third-party Intellectual Property Rights by the Client (except to the extent such Claims arise out of or result from or are based upon use of Kemwell's Pre-exiting IPR and manufacturing process), (d) any actual or alleged injury to person or property or death resulting from the possession, use or consumption by any person of any Product or Product sample supplied by Kemwell under this Agreement to the Client, provided that such Product or samples complied with the Specifications and Quality Agreement, or (e) the Client's gross negligence or intentional misconduct or fraud, except in each case to the extent such Claims or Losses arise from gross negligence, intentional misconduct or fraud on the part of a Kemwell Indemnitee or a breach of this Agreement by Kemwell.

10.3. The indemnification rights of Parties under this Agreement are independent of, and in addition to, such other rights and remedies as each Party may have under Applicable Law, in equity or otherwise, including the right to seek specific performance or other injunctive relief, none of which rights or remedies shall be affected or diminished thereby. Notwithstanding anything mentioned in the foregoing paragraph, the right of indemnification under this Section 10 shall be the sole monetary remedy available to the Indemnified Parties. The Indemnified Party shall not be entitled to make more than one (1) claim under this Section 10 in relation to the same Loss.

10.4. Indemnification Procedure. If either Party ("**Indemnified Party**") receives any written notice which such Indemnified Party believes is the subject of an indemnity Claim hereunder by the other Party ("**Indemnifying Party**"), the Indemnified Party shall, [***] and in any event within [***], give notice thereof to the Indemnifying Party, provided that the failure to give timely notice to the Indemnifying Party as contemplated hereby shall not release the Indemnifying Party from any liability to the Indemnified Party unless the Indemnifying Party is prejudiced by such failure or such failure results in an increase in the liability of the Indemnifying Party in relation to the indemnity Claim. The Indemnifying Party shall have the right to assume the defence of such Claim [***]. If the Indemnifying Party does not so assume the defence of such Claim, the Indemnified Party may assume the defence with counsel of its choice. If the Indemnifying Party so assumes the defence, it shall have absolute control of the litigation; the Indemnified Party may, nevertheless, participate therein through counsel of its choice and [***]. The Party not assuming the defence of any such Claim shall render all reasonable assistance to the Party assuming such defence. No such Claim shall be settled other than by the Party defending the same, and then only with the consent of the other Party, which consent shall not be unreasonably withheld; provided that the Indemnified Party shall have no obligation to consent to any settlement of any such claim which:

(a) imposes on the Indemnified Party any liability or obligation which cannot be assumed or performed in full by the Indemnifying Party;

(b) does not unconditionally release the Indemnified Party;

(c) does require a statement as to or an admission of fault, culpability or failure to act by or on behalf of Indemnified Party or any of its Affiliates; or

(d) does impose any restrictions on the conduct of business by the Indemnified Party or its Affiliates.

10.5. Each Party shall use [***] to avoid or mitigate any losses or liabilities that would otherwise be suffered or incurred by such Party and eligible for indemnification under this Agreement by the other Party.

10.6. Notwithstanding anything to the contrary contained herein, any claim for indemnity under this Section indemnifying Party shall be made within the applicable statutory period of limitation. For avoidance of doubt, the indemnifying Party shall not have any indemnification obligations and the indemnification obligations of the indemnifying Party shall cease, with respect to any claim for indemnity under this Section 10, if such claim for indemnity under this Section 10 is made after the applicable statutory period of limitation.

11. LIMITATION OF LIABILITY

11.1. Neither Party shall be liable to the other Party for any incidental, indirect, punitive, consequential (including without limitation, lost profits), exemplary or special damages of any type, arising in connection with this Agreement, whether or not foreseeable and whether such damages arise in tort, contract, equity, strict liability, or otherwise, even if the Party has been advised of the possibility of such damages.

11.2. Except in the event of and to the extent of (a) damages awarded to a third party in connection with the indemnification provisions set forth in Section 10.1 and 10.2 above or (b) a breach of Applicable Law, confidentiality obligations or the Intellectual Property Rights of the other Party and (c) damages arising from the gross negligence, fraud or wilful misconduct of a Party or its Affiliates, either Party's maximum aggregate liability under an SOW for damages of any kind relating to this Agreement or its subject matter shall not exceed [***].

11.3. In the event of claims or damages arising out of: (a) damages awarded to a third party in connection with the indemnification provisions set forth in Section 10.1 and 10.2 above or (b) a breach of Applicable Law, confidentiality obligations or the Intellectual Property Rights of the other Party and (c) damages arising from the gross negligence, fraud or wilful misconduct of a Party or its Affiliates, either Party's maximum aggregate liability under an SOW for damages of any kind relating to this Agreement or its subject matter shall not exceed [***].

12. FORCE MAJEURE

12.1. Except for each Party's payment, confidentiality and indemnity obligations, the obligations of either Party under this Agreement shall be suspended during each period of delay caused by matters such as acts of God including fire, flood, power failures, storm, strike, lockout or other labour dispute, epidemics, riot, acts of war or terrorism, restrictions by an Authority which are beyond the control of the Party obligated to perform (each, a "**Force Majeure Event**"). A Force Majeure Event shall not include lack of funds, bankruptcy or other financial cause or disadvantage.

12.2. A Force Majeure Event shall be deemed to continue only so long as the affected Party shall be using its commercially reasonable effort to overcome such condition. If either Party shall be affected by a Force Majeure Event, such Party shall give the other Party a notice thereof within seven (7) Business Days of its occurrence, which notice shall contain the affected Party's estimate of the duration of such condition (to the extent reasonably practicable) and a description of the steps being taken or proposed to be taken to overcome such Force Majeure Event.

12.3. Any delay in the performance of the Services occasioned by any such cause shall not constitute a default under this Agreement, and the obligations of the Parties shall be suspended during the period of delay so occasioned. During any period of any Force Majeure Event, the Parties affected by such Force Majeure Event shall take any reasonable action necessary to mitigate the effects of such Force Majeure Event.

12.4. If a Party is unable to resume performance of its Services under this Agreement for a period of more than three (3) months, the other Party shall have the right to terminate this Agreement by serving a prior written notice to this effect on the other Party. Upon such termination, the provisions set out in Section 20.6 shall apply.

13. INSURANCE

13.1. Kemwell Insurance. Kemwell shall secure and maintain in full force and effect throughout the Term and reasonable period thereafter relevant liability insurance policies including but not limited to a general liability insurance for appropriate amounts of adequate coverage in accordance with good commercial practice and sufficient to support its obligations under this Agreement.

13.2. Client Insurance. The Client shall secure and maintain a general liability insurance of adequate coverage in accordance with good commercial practice and sufficient to support its obligations under this Agreement during the Term and for a reasonable period thereafter. The Client shall be responsible for securing and maintaining insurance for the Specific Assets against theft, fire, flood and similar causes that are likely to damage or cause a loss of Specific Assets. Upon the Client's request and subject to the approval of the insurance amount by the Client, Kemwell shall secure and maintain adequate insurance policies for the Specific Assets, and the Client shall reimburse Kemwell of the cost of such insurance policies, [***], subject to submission of supporting documents, within [***] of notice from Kemwell to the Client after such payment.

14. OTHER COVENANTS

14.1. Reports of auditing accounts

(a) Each Party shall keep records and maintain all accurate accounts so as to enable the other Party to verify amounts payable pursuant to this Agreement.

(b) Each Party reserves the right to check and conduct an audit of the accounts [***] and the records [***] a year. In order to check and conduct the auditing, such Party may appoint its employees or other assigned personnel who can act on behalf of such Party to do the necessary job. All audits shall be performed in a manner intended to minimise disruption to the other Party's business.

(c) If any audit reveals that a Party has overpaid any amounts to the Party, the other Party will remit to such Party such amounts due within [***] after receiving a communication in this regard.

14.2. Each Party shall use its commercially reasonable efforts to take all action and to do all things necessary, proper or advisable to consummate and make effective the transactions contemplated by this Agreement.

14.3. Each Party shall comply with all Applicable Laws applicable to its activities under this Agreement.

14.4. During the Term of this Agreement, Kemwell shall maintain in full force and effect all appropriate Authorisations for performance of the Services and manufacturing and production of the Products under this Agreement.

14.5. Client shall ensure that all materials provided by the Client for use in the performance of the Services shall be free of defects and contaminants and are fit for use in the performance of the Services.

15. NOTICES

15.1. Any notice and other communications provided for in this Agreement shall be in writing and signed by or on behalf of the Party giving it and should be addressed for the attention of the relevant Party. Any such notice and other communication shall be first transmitted by electronic transmission and then confirmed by internationally recognised courier service or registered mail, in the manner as elected by the Party giving such notice to the following addresses:

(a) In the case of notices to the Client:

Address:	500 W. 5th Street, Suite 1200, Austin, Texas 78701, USA
Attention:	General Counsel
Email:	[***]

with a copy to:

Address:	[***]
Attention:	[***]
Email:	[***]

(b) In the case of notices to Kemwell:

Address:	[***]
Attention:	[***]
Email:	[***]

15.2. All notices shall be deemed to have been validly given on (a) the Business Day immediately after the date of transmission with confirmed answer back, if transmitted by electronic transmission, or (b) the Business Day of receipt, if transmitted by courier or registered airmail.

15.3. Any Party may, from time to time, change its address or representative for receipt of notices provided for in this Agreement by giving to the other Party a prior written notice.

16. INDEPENDENT CONTRACTOR

Kemwell shall perform the Services as an independent contractor of the Client. The relationship between the Parties shall be on a principal-to-principal basis and shall not constitute a partnership, joint venture or agency nor constitute either Party as the agent, employee or legal representative of the other. The Parties agree that neither shall have power or right to bind or obligate the other, nor shall either hold itself out as having such authority.

17. ENTIRE AGREEMENT, AMENDMENT, CONSTRUCTION, PRECEDENCE

This Agreement, together with the Exhibits attached hereto, the Quality Agreement and the SOWs constitute the entire agreement between the Parties and supersede all prior and contemporaneous negotiations, representations, commitments, agreements and understandings between the Parties (whether written or oral) relating to the subject matter hereof. This Agreement shall not be amended or modified without the mutual written consent of both Parties. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply. In the event of any conflict among the components of this Agreement, the following order of precedence shall apply: (i) the terms and conditions of this Agreement, (ii) the Quality Agreement and (iii) SOW, unless the Quality Agreement or the SOW specifically states that it takes precedence.

18. CHOICE OF LAW

18.1. This Agreement shall be governed by and construed in accordance with the laws of England and Wales. Subject to the provisions of Section 18.2, both Parties herein submit to the exclusive jurisdiction of the courts of London, England with respect to any disputes under this Agreement.

18.2. The Parties agree that they shall [***] work towards implementation of this Agreement and any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which such dispute shall be referred to arbitration to be conducted in accordance with the Rules of London Court of International Arbitration (LCIA) ("**Rules**"). The arbitration shall be held in London, England and shall be conducted in English by one arbitrator, appointed by both the Parties in accordance with said Rules. The decision of such arbitrator shall be written, reasoned, final, binding and conclusive on the Parties, and award thereon may be enforced in any court having jurisdiction over the Parties and the subject matter hereof. All expenses and fees of the arbitrator and expenses for hearing facilities and other expenses of the arbitration will be borne [***] unless the Parties agree otherwise or unless the arbitrator in the award assesses such expenses against one of the Parties or allocates such expenses [***]. Each of the Parties will bear its own counsel fees and the expenses of its witnesses except (i) to the extent otherwise provided in this Agreement or by Applicable Laws or (ii) to the extent the arbitrator in their discretion determines for any reason to allocate such fees and expenses among the Parties in a different manner.

19. ASSIGNMENT AND DELEGATION

19.1. Assignment. This Agreement shall not be assigned in whole or in part by either Party without the prior written consent of the other; provided, however, either Party may assign this Agreement in its entirety without the other Party's consent, upon written notice to the other Party, as part of: (a) the sale of all or substantially all of the assets or the entire business to which this Agreement relates, or (b) a merger, consolidation, reorganisation or other combination with or into another person or entity, in each case, pursuant to which the surviving entity or assignee assumes in writing the assigning or merging Party's obligations hereunder. Any attempt to assign, or purported assignment of, this Agreement in contravention to this Section 19.1 shall be *void ab initio* and of no effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

19.2. Delegation. Neither Party may delegate any performance under this Agreement; however, performance of the Services hereunder may be delegated or subcontracted with the prior written consent of the other Party.

20. TERM AND TERMINATION

20.1. Term of the Agreement. The term of this Agreement shall be from the Effective Date until the fifth (5th) anniversary thereof, unless earlier terminated as provided herein or extended by mutual agreement of the Parties (the "**Term**").

20.2. (a) Termination by Client. Client may terminate this Agreement or an SOW without cause at any time upon thirty (30) days' prior written notice to Kemwell.

(a) Termination by mutual agreement. This Agreement may be terminated at any time upon mutual written agreement of both Parties.

20.3. Termination for material breach. Agreement may be terminated by either Party upon sixty (60) days' written notice to the other Party in the event of a material breach of this Agreement by the other Party and which material breach is not cured within such sixty (60)-day period. Notwithstanding the foregoing, in the event the other Party disputes that it is in material breach of this Agreement, subject to such sixty (60)-day period, the dispute will be referred to the attention of senior representative nominated by Kemwell on one side and the senior representative of the Client on the other side (the "**Executive Officers**"). The Executive Officers will meet as soon as reasonably possible thereafter and in good faith attempt to resolve such dispute and attempt to resolve the underlying breach. If the Executive Officers are unable to resolve such dispute or resolve the underlying breach within thirty (30) days after such matter is referred to them, the dispute regarding whether there has been a material breach of the Agreement will be referred for resolution by arbitration pursuant to Section 18.2. If the arbitrator determines that the Agreement has been materially breached and the breaching Party fails to cure such breach within sixty (60) days of such determination, the non-breaching Party shall thereafter be entitled to terminate this Agreement without further delay and pursue any rights and remedies available to such Party (at law or in equity). Subject to Section 20.6(c), the Parties agree that, pending determination by the arbitrator, both Parties shall cease to perform their respective obligations under this Agreement unless the arbitrator, upon specific motion of either Party, orders that in the interim period pending completion of the arbitration the Parties shall continue to perform their respective obligations

under this Agreement. If any notice of breach is for breach of an SOW, such notice shall note the specific SOW under which such breach is claimed.

20.4. Termination for Insolvency, Bankruptcy. This Agreement may be terminated upon written notice by a Party in the event: (i) the other Party voluntarily enters into bankruptcy proceedings or any step is taken to appoint a manager, receiver, administrative receiver, administrator, trustee or other similar officer in respect of such Party or any of its assets; (ii) the other Party makes an assignment for the benefit of creditors or it convenes a meeting of its creditors or makes or proposes any arrangement or composition with its creditors; (iii) a petition is filed against the other Party under a bankruptcy law, a corporate reorganisation law, or any other law for relief of debtors or similar law analogous in purpose or effect, which petition is not stayed or dismissed within thirty (30) days of filing thereof; (iv) the other Party enters into liquidation or dissolution proceedings or a liquidator, resolution professional, administrator, trustee in bankruptcy, receiver or the like is appointed by an Authority with respect to any assets of the other Party, which appointment is not vacated within one hundred and eighty (180) days; or (v) it is unable to, or admits its inability to, pay its debts as they fall due.

20.5. Termination for Technical Difficulties or Force Majeure. This Agreement may be terminated in accordance with Section 3.3 or Section 12. Upon such termination, Kemwell will promptly stop or scale down the affected portion of the relevant SOW and cease to incur any further or additional expenses in relation to such terminated portion of the SOW.

20.6. Effects of Termination.

(a) Upon expiration or termination of this Agreement for any reason, each Party shall, as soon as practicable, but in any event within thirty (30) Business Days of the expiration or effective date of termination, as the case may be, return to the other Party or, at the discretion of the other Party, destroy, all the Confidential Information, Intellectual Property Rights, other information including artwork and material which it possesses that belongs to the other Party. In addition, Kemwell shall, as practicable, but in any event within thirty (30) Business Days (or such extended period mutually agreed to between the Parties in writing) of the expiration or effective date of termination, as the case may be, return to the Client or its nominee designated by the Client or, at the discretion of the Client, destroy, all the Client Material and Specific Assets in Kemwell's possession. Upon termination of this Agreement and in any event no later than seven (7) Business Days from the date of expiration or effective date of termination of this Agreement, as the case may be, Kemwell will furnish to the Client a complete inventory of all work in progress, raw materials and consumables and an inventory of all Products processed pursuant to the relevant SOW and shall delivery/return the same to the Client no later than thirty (30) Business Days from the expiration or effective date of termination of this Agreement, as the case may be. Any costs incurred in the return of materials shall be borne by the Party to whom such material belongs and Kemwell should also confirm in writing that they have disclosed to the Client, the existence of any Client Inventions as of the date of the termination and shall transfer all such Client Invention to the Client no later than five (5) Business Days from the expiration or effective date of termination of this Agreement, as the case may be.

(b) Upon termination of this Agreement by any Party or by mutual consent of the Parties, the Client shall pay Kemwell a final undisputed sum (as confirmed by Kemwell in writing and agreed to by the Client) calculated by reference the Services performed in accordance with this Agreement until the date of termination of the Agreement, any raw-material purchases (purchased upon prior written consent of the Client or in accordance with the SOW) made until the termination of the Agreement and non-cancellable expenses incurred by Kemwell (provided such expenses are incurred upon prior written consent of the Client or are incurred in accordance with the SOW) until the termination of the Agreement. The aforesaid undisputed payments shall be made by the Client to Kemwell within [***] of receipt of such invoice upon termination of the Agreement provided such invoice is not disputed by the Client. If upon the effective date of termination the Client has advanced funds which are unearned by Kemwell, Kemwell shall set-off such undisputed amount against payments due to it and repay any amount remaining to the Client within [***] of the effective date of termination.

(c) Upon termination of this Agreement by the Client pursuant to Section 20.3 or Section 20.5 (except in the event of termination attributable to Force Majeure or Technical

Difficulty not within the control of Kemwell), the Client shall have the right to either on its own or through its Affiliate appoint a third party to continue performance of the Services and Kemwell shall, [***] provide all such reasonably necessary support as may be required by the Client for the smooth transition of the Services from Kemwell to the Client or such of Client's Affiliate or third party designated by the Client. Upon termination of this Agreement by the Client pursuant to Section 20.5 (in the event of termination attributable to Force Majeure or Technical Difficulty not within the control of Kemwell), the Client shall have the right to either on its own or through its Affiliate or appoint a third party to continue performance of the Services and Kemwell shall, [***] provide all such reasonably necessary support as may be required by the Client for the smooth transition of the Services from Kemwell to the Client or such of Client's Affiliate or third party designated by the Client. In case of termination for any other cause, Kemwell agrees to provide transitional support on a [***] basis to the Client to enable the Client to undertake the Service delivery by itself or through a third Party [***]. In each of the aforesaid cases, Kemwell will also promptly stop or scale down the affected portion of the relevant SOW and use its [***] efforts to avoid additional expenses, unless otherwise agreed to by the Client in writing.

(d) The termination of this Agreement for any reason whatsoever or expiry of this Agreement shall not relieve either Party of its obligations to the other in respect of: (a) Confidentiality; (b) consents for advertising or publications purpose; (c) Indemnification; and (d) Intellectual Property. Further the Parties hereby agree that the terms of this Agreement which by their nature should survive termination of this Agreement, shall survive termination or expiry, as the case may be, of this Agreement and shall continue to be binding on both of the Parties.

(e) The termination or expiry, as the case may be, of this Agreement shall be without prejudice to any claim or rights of action, including but not limited to the right to seek damages, previously accrued to any Party hereto against the other Party.

(f) Except as otherwise expressly set forth herein, any termination or expiration of this Agreement shall be without prejudice to any rights which shall have accrued to the benefit of either Party and shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein or, if no period is provided therein, then such obligations shall remain in full force and effect indefinitely.

21. ANTI-CORRUPTION LAWS

Each Party will, and will cause its subcontractors performing any Services or obligations under this Agreement, to comply with the U.S. Customs & Trade Partnership Against Terrorism (CTPAT) and with the laws and regulations relating to anti-corruption and anti-bribery, including the U.S. Foreign Corrupt Practices Act, the OECD Convention Against the Bribery of Foreign Officials in International Business Transactions and the Prevention of Corruption Act 1988 (collectively, the "**Anti-Corruption Laws**"). Each Party acknowledges that it is its own responsibility to be familiar with, and comply with, the provisions of the Anti-Corruption Laws. Each Party represents and warrants that neither it, nor anyone acting on its behalf, will give, offer, agree or promise to give any money or thing of value to anyone as an inducement or reward for favorable action or forbearance from action or the exercise of influence (a) to any government official or employee, (b) to any political party, official of a political party, or candidate, (c) to an intermediary of any of the forgoing, or (d) to any other person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license. Each Party understands and agrees that the other Party may immediately suspend its performance under this Agreement, in its sole discretion and without notice, if the actions or inactions of such Party is in breach of the Anti-Corruption Laws.

22. SEVERABILITY

In the event that any one or more of the provisions of this Agreement should be held for any reason by any court or Authority having final jurisdiction over this Agreement, or over any of the Parties to this Agreement, to be invalid, illegal, or unenforceable, such provision or provisions shall be reformed to approximate as nearly as possible the intent of the Parties,

and if not reformable, shall be divisible and deleted in such jurisdictions; elsewhere, this Agreement shall not be affected.

23. AMENDMENTS, WAIVER AND REMEDIES

The delay or waiver (or single or partial exercise) by either Party hereto of any right, power, or privilege hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right, power, or privilege hereunder or of any other breach by or failure of such other Party, whether of a similar nature or otherwise. Any such waiver must be made in writing. Except as may otherwise be specifically set forth in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or equity. No Party shall have any right of set off with respect to amounts it has an obligation to pay hereunder. No provision of this Agreement shall in any way inure to the benefit of any third person so as to constitute to any such person a third-party beneficiary of this Agreement or otherwise give rise to any cause of action in any person not a Party hereto. No amendment to this Agreement will be effective unless it is in writing (referencing the provisions to be amended) and signed by both the Parties, and any such amendment will be binding on both the Parties.

24. COUNTERPARTS

This Agreement, any SOW, the Quality Agreement, and any other attachment may be executed in counterparts, each of which will be deemed an original but all of which together will constitute a single instrument. Delivery of a counterpart of this Agreement by way of an e-mail attachment shall be an effective mode of delivery. Signature pages of this Agreement may be executed and exchanged by email, in .pdf format, DocuSign and that any such digital/e-signature shall be given the same legal force and effect as the original handwritten signatures without affecting the validity thereof.

25. FEES AND EXPENSES

Except as otherwise expressly provided in this Agreement, each Party is responsible for and shall bear the fees, charges, costs and expenses incurred by such Party in connection with or relating to this Agreement (including the negotiation, preparation, review, entry into, delivery or performance of this Agreement). Notwithstanding the foregoing, the Parties shall jointly and in equal proportion bear costs for stamp duty payable on this Agreement.

26. SPECIFIC PERFORMANCE

Each Party may, without posting any bond or giving any other assurance or the necessity of proving the inadequacy of monetary damages (and without limiting the availability of other remedies, whether at law or in equity), sue for specific performance, obtain an injunction, or seek any other temporary, preliminary or permanent relief as a court of competent jurisdiction deems necessary or appropriate to enforce the performance of, or restrain the other Party from not complying with, the obligations under this Agreement.

[signatures on next page]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

In Witness Whereof, the Parties by their authorised representatives execute this Agreement as of the Effective Date.

KEMWELL BIOPHARMA PVT. LTD.	**SHATTUCK LABS, INC.**
Signature: /s/ Anurag Bagaria	Signature: /s/ Taylor Schreiber
Name: Anurag Bagaria	Name: Taylor Schreiber, M.D., Ph.D.
Title: Chairman & CEO	Title: Chief Executive Officer

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

EXHIBIT I

[***]

Shattuck Labs, Inc. Insider Trading Policy

1. INTRODUCTION

Federal and state laws prohibit buying, selling, gifting or making other transfers of securities by persons who have material information that is not generally known or available to the public. These laws also prohibit persons with such material nonpublic information ("MNPI") from disclosing this information to others who trade. Trading while in possession of MNPI is often referred to as "insider trading."

Shattuck Labs, Inc. (the "Company") has adopted the following policy (this "Policy") regarding trading in securities by directors, officers, employees and consultants (together, "Company Personnel") as well as their family members who reside with them, anyone else who lives in their household, and any family members who do not live in their household but whose transactions in Company securities (as defined below) are directed by them or are subject to their influence or control (collectively, "Family Members"), and corporations or other business entities controlled, influenced or managed by them or their Family Members, and trusts for which such persons are a trustee or in which they have a beneficial or pecuniary interest (collectively, "Controlled Entities," and together with "Company Personnel" and "Family Members," "Insiders"). Unless otherwise indicated, all references to "you" in this Policy should be read to include all of your Family Members and Controlled Entities. However, this Policy does not apply to any entity that invests in securities in the ordinary course of its business, for example, a venture or other investment fund, if, and only if, the entity has certified to the Company that it has established its own insider trading controls and procedures in compliance with applicable securities laws and with respect to trading in the Company's securities.

No Exceptions. The prohibition against trading while in possession of MNPI is absolute and unconditional. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to high standards of conduct.

Individual Responsibility. You are responsible for ensuring that you (as well as your Family Members and Controlled Entities) do not violate federal or state securities laws or this Policy. We designed this Policy to promote compliance with the federal securities laws and to protect the Company and you from the serious liabilities and penalties that can result from violations of these laws.

Consequences for Violating Insider Trading Laws. If you violate insider trading laws, you may have to pay civil fines for up to three times the profit gained or loss avoided by such trading, as well as criminal fines of up to $5 million. You also may have to serve a jail sentence of up to 20 years. In addition, the Company may face civil penalties up to the greater of $1 million, or three times the profit gained or loss avoided as a result of your insider trading violations, as well as criminal fines of up to $25 million.

Both the Securities and Exchange Commission ("SEC") and The Nasdaq Stock Market ("Nasdaq") are very effective at detecting and pursuing insider trading cases. The SEC has successfully prosecuted cases against employees trading through foreign accounts, trading by family members and friends, and trading involving only a small number of shares. Therefore, it

is important that you understand the breadth of activities that constitute illegal insider trading. This Policy sets out the Company's policy in the area of insider trading and should be read carefully and complied with fully.

All Company Personnel will be required to certify their understanding of and intent to comply with this Policy by signing the Receipt and Acknowledgement attached hereto periodically.

This Policy will be reviewed, evaluated, and revised by the Company from time to time in light of regulatory changes, developments in the Company's business and other factors.

II. POLICIES AND PROCEDURES

A. Trading Policy

1. *General Prohibition*. You may not buy, sell, gift or otherwise transact in securities of the Company or a Company Counterparty (as defined below) when you are aware of MNPI about that company or its securities that you learned in the course of your employment or service with the Company. Company Counterparties include companies with which the Company has a preexisting or prospective relationship, such as the Company's customers, distributors, suppliers, contract research, manufacturing, licensing or other collaboration partners, companies in which the Company has an investment or a firm with which the Company is negotiating a major transaction, such as a joint venture, licensing transaction, collaboration arrangement or material acquisition or disposition (a "Company Counterparty" or "Company Counterparties").

2. *No Tipping*. You may not convey MNPI about the Company or a Company Counterparty or its securities that you learned in the course of your employment or service with the Company to others. You also may not suggest that anyone purchase or sell the Company's or a Company Counterparty's securities while you are aware of MNPI about that company or its securities. These practices, known as "tipping," also violate U.S. securities laws and can result in the same civil and criminal penalties that apply if you engage in insider trading directly, even if you do not receive any money or derive any benefit from trades made by persons to whom you passed MNPI. This Policy against "tipping" applies to information about the Company and its securities, as well as to information about Company Counterparties and its securities that you learned in the course of your employment or service with the Company. Persons with whom you have a history, pattern or practice of sharing confidences—such as family members, close friends and financial and personal counselors —may be presumed to act on the basis of information known to you; therefore, special care should be taken so that MNPI is not disclosed to such persons. This Policy does not restrict legitimate business communications on a "need to know" basis. MNPI, however, should not be disclosed to persons outside the Company unless you are specifically authorized to disclose such information and such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company.

3. *No Short-Term or Speculative Trading*. It is against Company policy for you to engage in short-term or speculative transactions in Company securities. As such, with respect to Company securities, you may not engage in: (a) short-term trading (generally

defined as selling Company securities within six months following a purchase); (b) short sales (selling Company securities you do not own); (c) transactions involving publicly traded options or other derivatives (such as trading in puts or calls with respect to Company securities); and (d) hedging transactions (such as "cashless" collars, forward sales, equity swaps and other similar arrangements). Additionally, because securities held in a margin account or pledged as collateral may be sold without your consent, if you fail to meet a margin call or if you default on a loan, a margin or foreclosure sale may result in unlawful insider trading. Because of this danger, you should exercise caution when purchasing Company securities on margin, borrowing against any account in which Company securities are held or pledging Company securities as collateral for a loan.

4. *Applying the Trading Policy*. As stated above, these restrictions also apply to your Family Members *and* Controlled Entities (except as exempted above). The SEC and federal prosecutors may presume that trading by Family Members or Controlled Entities is based on information you supplied and may treat any such transactions as if you had traded yourself. There is no exception for small transactions or transactions that may seem necessary or justifiable for independent reasons, such as the need to raise money for an emergency expenditure.

For purposes of this Policy, references to "trading" and "transactions" includes, among other things:

- purchases and/or sales of Company securities in public markets;
- sales of Company securities obtained through the exercise of employee stock options granted by the Company;
- making gifts of Company securities; and
- using Company securities to secure a loan.

Directors, officers, employees and consultants should consult the General Counsel (stocks@shattucklabs.com) if they have any questions.

5. *Company Transactions*. From time to time, the Company may engage in transactions in its own securities, including share issuances and repurchases. The Company's practices with respect to these transactions, which are overseen by the Finance and Legal departments (and approved by the Board of Directors or appropriate committee, if required or appropriate), are designed to promote compliance with applicable insider trading and other securities laws, rules, regulations and listing standards. Transactions pursuant to equity-based compensation arrangements are conducted in accordance with the terms of the plans and agreements.

B. What is "Material Nonpublic Information"? When is Information "Public"?

1. Material Information

Material information generally means information that a reasonable investor would consider important in making an investment decision to buy, hold, or sell securities. Either positive or negative information may be material. Any information that could reasonably be expected to affect the Company's or a Company Counterparty's stock price should be considered material. Depending on the circumstances, common examples of information that may be material include:

- significant new product developments, innovations or discoveries;
- pending U.S. Food and Drug Administration, European Medicines Agency or other regulatory action;
- clinical data or significant interactions, approval or rulings by a regulatory agency relating to the Company or a Company product;
- status of pre-clinical or clinical studies;
- earnings, revenue, or similar financial information;
- unexpected financial results;
- unpublished financial reports or projections;
- extraordinary borrowing or liquidity problems;
- changes in control or sale of all or part of the Company's business;
- changes in directors, senior management or auditors;
- information about current, proposed, or contemplated transactions, business plans, financial restructurings, acquisition targets or significant expansions or contractions of operations;
- changes in dividend policies or the declaration of a stock split or the proposed or contemplated issuance, redemption, or repurchase of securities;
- negotiations regarding an important license, distribution agreement, joint venture or collaboration agreement;
- material defaults under agreements or actions by creditors, clients, or suppliers relating to a company's credit rating;
- information about major contracts;
- product recalls;
- impending financial problems;

- the interruption of production or other aspects of a company's business as a result of an accident, fire, natural disaster, or breakdown of labor negotiations;
- major environmental incidents;
- data breaches or other cybersecurity incidents;
- institution of, or developments in, major litigation, investigations, or regulatory actions or proceedings; and
- information specified above relating to Company affiliates and Company Counterparties.
- the imposition of a trading "blackout" by the Company on transactions in Company securities or the securities of a Company Counterparty.

Federal and Nasdaq investigators will scrutinize a questionable trade after the fact with the benefit of hindsight, so you should always err on the side of deciding that the information is material and not trade. The mere fact that a person is aware of MNPI is a bar to trading. It is no excuse that such person's reasons for trading were not based on the MNPI. If you have questions regarding specific transactions, please contact the General Counsel.

2. Nonpublic Information

Nonpublic information is information that is not generally known or available to the public. We consider information to be available to the public only when:

- it has been released to the public by the Company through appropriate channels (e.g., by means of a press release, a filing with the SEC or a widely disseminated statement from a senior officer); and
- enough time has elapsed to permit the investment market to absorb and evaluate the information. As a general rule, you should consider information to be nonpublic until two full trading days have lapsed following the time of public disclosure.

The fact that rumors, speculation, or statements attributed to unidentified sources are public is insufficient to be considered "generally available to the public" even when the information is accurate.

C. Unauthorized Disclosure; Prohibition on Certain Public Speaking

All Company Personnel must maintain the confidentiality of Company information for competitive, security and other business reasons, as well as to comply with securities laws. All information you learn about the Company or its business plans is potentially nonpublic information until it is publicly disclosed. You should treat this information as confidential and proprietary to the Company. You may not disclose it to others, such as Family Members, other relatives, or business or social acquaintances.

In addition, you are prohibited from participating as an "expert," consultant, advisor, and/or in any capacity for an "expert network" and/or any other outside firm which compensates individuals for speaking with investors and other investment professionals. This prohibition is designed to protect the Company, its stockholders and you. Indeed, United States criminal authorities and the SEC have prosecuted numerous public company employees who received monetary compensation by expert networks to speak with investors and disclose confidential company information which investors then used for trading purposes.

Legal rules govern the timing and nature of our disclosure of material information to outsiders or the public. Violation of these rules could result in substantial liability for you, the Company and its management. For this reason, we permit only specifically designated representatives of the Company to discuss the Company with the news media, securities analysts and investors and only in accordance with the Company's Guidelines For Public Disclosures And Communications With The Investment Community. If you receive inquiries of this nature, refer them to the Chief Financial Officer ("CFO") or General Counsel. At any time when the Company does not have an active CFO, the duties and responsibilities assigned to the CFO under this policy shall be performed by the principal financial officer.

D. When and How to Trade Company Stock

1. Overview

Directors, officers, C-level employees, and certain other employees and consultants who are so designated from time to time (such officers and designated employees and consultants, "Restricted Employees") are for purposes of this Policy required to comply with the restrictions covered below. Even if you are not a director or a Restricted Employee, however, following the procedures listed below may assist you in complying with this Policy.

2. Blackout Periods

From time to time due to certain developments relating to MNPI, the Company may implement special blackout periods during which the Company may notify particular individuals that they should not engage in any transactions involving the purchase or sale of Company securities or the securities of a Company Counterparty. If you are subject to a special blackout period, you should not trade in the applicable company's securities during such time and you should not disclose to others the fact that you are prohibited from trading.

However, it is not the Company's policy to impose special blackout periods every time that MNPI exists, or every time that a director, officer, C-level employee, or certain other employees and consultants may be in the possession of MNPI. Thus, the absence of a special blackout should not be interpreted as permission to trade. In addition, if you are subject to the Company's pre-clearance policy (described below), you must pre-clear transactions even if you initiate them while a special blackout period is not in place.

Even if a special blackout period is in place, you may exercise Company stock options if no shares are to be sold — you may not, however, effect sales of stock issued upon the exercise of stock options (including same-day sales and cashless exercises). Generally, all pending purchase and sale orders regarding Company securities that could be executed while a special blackout

period is not in place must be cancelled before a special blackout period is implemented so as to avoid any purchases and sales during such period.

In light of these restrictions, if you expect a need to sell Company stock at a specific time in the future, including executing sales to satisfy tax withholding obligations in connection with the exercise of stock options, vesting of restricted stock or settlement of restricted stock units in the future, you may wish to consider entering into a prearranged Rule 10b5-1 trading plan (as discussed below).

3. Pre-clearance

The Company requires its directors and Restricted Employees to obtain prior approval from the General Counsel (or, in the General Counsel's absence, the General Counsel's designee) before effecting any purchase, sale, gift or other trading of Company securities.[1] Directors and Restricted Employees may ask for pre-clearance by sending an email to stocks@shattucklabs.com. The pre-clearance policy applies to directors and Restricted Employees, including their Family Members and Controlled Entities, even if they are initiating a transaction while a special blackout period is not in place.

If a transaction is approved under the pre-clearance policy, the transaction must be executed by the last close of regular trading that is not more than three calendar days after the approval is obtained, but regardless, the transaction may not be executed if you acquire MNPI concerning the Company during that time. If the transaction is not completed within the period described above, the transaction must be approved again before it may be executed.

If a proposed transaction is not approved under the pre-clearance policy, you may not transact in Company stock, and you should not inform anyone within or outside of the Company of the restriction. Any transaction under a Rule 10b5-1 trading plan will not require pre-clearance at the time of the transaction, but the adoption, amendment, modification or termination of any such Rule 10b5-1 trading plan is subject to pre-clearance.

4. Exceptions

The restrictions contained in this Policy shall not apply to:

- the exercise of Company stock options if (a) no shares are to be sold to third parties or (b) there is only a "net exercise" (defined as the Company withholding shares to satisfy your tax obligations or to cover the exercise price or equivalent);
- "sell to cover" transactions involving a sale of shares of common stock directed by the Company in its sole discretion in order to cover the Company's or such individual's or entity's withholding tax obligations in connection with the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;[1]

[1] Transactions by the General Counsel (or the General Counsel's Family Members and Controlled Entities) are required to be approved in advance by the Chief Executive Officer (the "CEO") or CFO.

- the vesting of Company stock options, restricted stock, restricted stock units or other equity incentive awards according to their terms;
- the withholding of shares to satisfy the exercise price or a tax withholding obligation upon the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;
- transferring shares to an entity that does not involve a change in the beneficial ownership of the shares (for example, transferring shares from one brokerage account to another brokerage that you control);
- sales of Company securities as a selling stockholder in a registered public offering, including a "synthetic secondary" offering, in accordance with applicable securities laws; or
- any other purchase of Company securities from the Company or sale of Company securities to the Company in accordance with applicable securities and state laws.

To the extent applicable and such elections are permitted, your elections regarding participation in "net exercise," or "sell to cover" transactions, including changes from any defaults established by the Company, may not be made during a blackout period or while you otherwise are in possession of MNPI.

E. Rule 10b5-1 Trading Plans

Rule 10b5-1 provides an affirmative defense from insider trading liability if trades occur pursuant to a prearranged trading plan that meets specified conditions (a "10b5-1 Plan"). It is possible to prearrange trades in Company securities by entering into a 10b5-1 Plan. A 10b5-1 Plan must either specify the number of securities to be bought or sold, along with the price and the date, or provide a written formula for determining this information. Alternatively, a 10135-1 Plan can delegate investment discretion to a third party, such as a broker, who then makes trading decisions without further input from the person implementing the 10b5-1 Plan. A 10b5-1 Plan must be established at a time when you are not aware of any MNPI and must not permit you to exercise any subsequent control or influence over how, when or whether the purchases or sales are made. Because the SEC rules on 10b5-1 Plans are complex, you should consult the Company's "Guidelines for Rule 10b5-1 Trading Plans" set forth in Appendix A as well consult with your broker and be sure you fully understand the limitations and conditions of the rules before you establish a trading plan.

All 10b5-1 Plans must comply with the Company's "Guidelines for Rule 10b5-1 Trading Plans" set forth in Appendix A and be reviewed and approved in advance by the General Counsel.

F. Noncompliance

Anyone subject to this Policy who fails to comply with this Policy will be subject to appropriate disciplinary action, up to and including termination of employment.

G. Post-Termination Transactions

This Policy will continue to apply to your transactions in Company securities after your employment or service with the Company has terminated until such time as you are no longer aware of MNPI or until that information has been publicly disclosed or is no longer material.

Questions about this Policy should be directed to the General Counsel.

* * * * *

Policy last amended on November 5, 2025.

RECEIPT AND ACKNOWLEDGMENT

I, _____, hereby acknowledge that I have received and read a copy of the Shattuck Labs, Inc. Insider Trading Policy (this "Policy"). I agree to comply with this Policy and certify that I will communicate with all members of my household to inform them of the obligations in this Policy that apply to them. I understand that violation of this Policy may subject me to discipline by Shattuck Labs, Inc. up to and including termination for cause.

Signature Date

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-249555, 333-254340, 333-263552, 333-269955, 333-277530, and 333-286149) on Form S-8 and (Nos. 333-276677, 333-290355, and 333-292697) on Form S-3 of our report dated March 5, 2026, with respect to the financial statements of Shattuck Labs, Inc.

/s/ KPMG LLP

Austin, Texas
March 5, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Taylor Schreiber, certify that:

1. I have reviewed this Annual Report on Form 10-K of Shattuck Labs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2026

By: /s/ Dr. Taylor Schreiber

Dr. Taylor Schreiber
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew R. Neill, certify that:

1. I have reviewed this Annual Report on Form 10-K of Shattuck Labs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2026

By: /s/ Andrew R. Neill

Andrew R. Neill
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Shattuck Labs, Inc. (the "Company") for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2026

By: /s/ Dr. Taylor Schreiber
Dr. Taylor Schreiber
Chief Executive Officer
(principal executive officer)

Date: March 5, 2026

By: /s/ Andrew R. Neill
Andrew R. Neill
Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Shattuck Labs, Inc. and will be retained by Shattuck Labs, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.