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, 2022
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**

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. ☐

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, 2022, was approximately $110,520,086, 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 in that 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 1, 2023, the registrant had 42,449,087 shares of common stock, $0.0001 par value per share, outstanding.

Documents Incorporated by Reference

The information required by Part III of this Report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2023, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this 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," "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," 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. Given the significant 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 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 and 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 platforms, including our ARC® and GADLEN™ product candidates and other product candidates, and the defense of such intellectual property rights;
- 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; and
- developments relating to our competitors and our industry, including competing product candidates and therapies

There may be other factors that may cause our actual results to differ materially from the forward-looking statements expressed or implied in this Annual Report on Form 10-K, including factors disclosed 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.

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, 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 expected.

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 events 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 an innovative clinical-stage biotechnology company pioneering the development of dual-sided fusion proteins as an entirely new class of biologic medicine. We have created a novel approach to immune modulation by designing biologics with structural characteristics that may not be achievable by existing therapeutic modalities, including monoclonal or bispecific antibodies. Compounds derived from our proprietary Agonist Redirected Checkpoint, or ARC®, platform simultaneously inhibit checkpoint molecules and activate costimulatory molecules with a single therapeutic.

Our lead product candidate, SL-172154, is designed to simultaneously inhibit the CD47/SIRPα macrophage checkpoint interaction and activate the CD40 costimulatory receptor to induce an antitumor immune response. Coupling CD40 activation with CD47 inhibition differentiates SL-172154 from all other clinical-stage CD47/SIRPα inhibitors in development, and in our published preclinical studies, SL-172154 resulted in superior antitumor immunity as compared to certain CD47/SIRPα inhibitors. We are pursuing a broad clinical development strategy in both solid and hematologic tumors, with multiple ongoing clinical trials. SL-172154 is in an ongoing Phase 1 clinical trial for the treatment of patients with ovarian cancer. We are also evaluating SL-172154 in an ongoing Phase 1 clinical trial for the treatment of patients with certain hematologic malignancies, including acute myeloid leukemia, or AML, and higher-risk myelodysplastic syndromes, or HR-MDS. We believe our clinical development plan may provide both first-in-class and best-in-class development opportunities for SL-172154.

We believe that data shared to date in human cancer patients have demonstrated that the unique protein engineering and physical properties of the ARC platform have led to a differentiated profile in terms of safety and on-target immune activation, demonstrated by unique pharmacodynamic findings, as compared to monoclonal or bispecific antibodies.

In addition to our clinical-stage ARC product candidate, we possess a deep pipeline of potential product candidates in preclinical development. As an example, SL-9258, an ARC compound in preclinical development, is designed to inhibit the TIGIT/PVR checkpoint interaction while simultaneously activating HVEM and LTβ costimulatory receptors.

Furthermore, our expertise in dual-sided fusion proteins has led to the development of a second novel platform technology. We call this our gamma delta T cell engager, or GADLEN™, platform. The most advanced compounds from this platform are a CD20-directed GADLEN and a B7-H3-directed GADLEN.

Longer-term, we are pursuing additional disease areas, including autoimmune diseases, where our dual-sided fusion protein platforms may provide advantages over current treatment modalities.

Our Pipeline

Our lead product candidate, SL-172154, is designed to simultaneously inhibit the CD47/SIRPα macrophage checkpoint interaction and activate the CD40 costimulatory receptor to induce an antitumor immune response. Coupling the costimulatory effect of CD40 activation with CD47 inhibition differentiates SL-172154 from other CD47/SIRPα inhibitors in clinical development. In clinical studies, we believe that SL-172154 has further differentiated from other CD47/SIRPα inhibitors both in terms of safety and tolerability and has demonstrated pharmacodynamic evidence of potent CD40 activation in human cancer patients.

We are conducting a Phase 1 clinical trial evaluating SL-172154 in patients with platinum-resistant ovarian cancer. In November 2021, at the 36th annual meeting of the Society for Immunotherapy Cancer, or the SITC Meeting, we announced initial data from 15 patients in the first four dose-escalation cohorts from our Phase 1A monotherapy dose-escalation clinical trial. These data demonstrated that SL-172154 was well tolerated through 3 mg/kg, with no treatment-related grade 3 or greater adverse events. Near-complete target occupancy on leukocytes was observed for both CD47 and CD40 at 3 mg/kg. We also observed pharmacodynamic activity, including dose-dependent margination of CD40 expressing leukocytes from the peripheral blood and dose-dependent increases in cytokines, such as IL-12, that are associated with antitumor immunity.

Subsequently, we completed the Phase 1A monotherapy dose-escalation clinical trial. We completed enrollment at the anticipated top dose level of 10 mg/kg, which was the maximum administered dose. A maximum tolerated dose was not reached in this clinical trial. The data collected through 10 mg/kg demonstrated that the pharmacodynamic activity, including increased serum cytokines and margination of CD40 positive leukocytes, observed at 3 mg/kg was maintained through 10 mg/kg, with no evidence of a "bell shaped" dose response curve. As a result, we selected the 3 mg/kg dose level to advance into the Phase 1B combination cohorts in platinum-resistant ovarian cancer patients.

We have initiated a Phase 1B clinical trial with two combination cohorts due to the observation of monotherapy immunologic activity across the administered dose range, as described above, and because multiple approved agents in the platinum-resistant ovarian cancer patient population are known to provide the prophagocytic, or "eat me", signal necessary to drive efficacy in the setting of CD47 inhibition. We have initiated a combination cohort evaluating SL-172154 in combination with liposomal doxorubicin, and a second combination cohort evaluating SL-172154 in combination with mirvetuximab soravtansine, in patients with platinum-resistant ovarian cancer. We expect to announce additional data from the Phase 1A monotherapy dose-escalation clinical trial and initial data from the Phase 1B cohort in combination with liposomal doxorubicin midyear 2023.

In addition to evaluating SL-172154 in solid tumors, we have initiated our clinical trial of SL-172154 in certain hematologic malignancies. We are conducting a Phase 1A/B clinical trial in patients with AML and HR-MDS, wherein patients will be enrolled into either a Phase 1A monotherapy cohort or Phase 1B combination cohort in a staggered parallel design. In HR-MDS and TP53 mutant AML, we intend to study SL-172154 in combination with azacitidine. In AML, we intend to study SL-172154 in combination with azacitidine and venetoclax. We expect to announce initial data, as monotherapy and in combination, from the dose-escalation portion of this Phase 1A/B trial in the first half of 2023.

We are leveraging our proprietary ARC and GADLEN platforms to discover and develop dual-sided, bi-functional fusion protein product candidates. We own, or have exclusively licensed, the intellectual property rights to our product candidates.

The following table highlights our clinical-stage product candidate and selected preclinical compounds:

		Domains				Stage of Development				
Platform	Program	Domain 1	Domain 2	Indications	Combination Agents	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Clinical-stage pipeline										
ARC	SL-172154	SIRPα	CD40L	Ovarian Cancer [1]	Liposomal Doxorubicin					
					Mirvetuximab Soravtansine					
				AML and HR-MDS [2]	Azacitidine +/- Venetoclax					
Preclinical-stage pipeline										
ARC	Multiple	Multiple		Oncology						
GADLEN	Multiple	γδ TCR	CD20	Autoimmune/Oncology						
		γδ TCR	B7H3	Oncology						

1. Advanced platinum-resistant ovarian cancer
2. Acute Myeloid Leukemia (AML) and Higher-Risk Myelodysplastic Syndromes (HR-MDS)

In addition to our clinical-stage ARC product candidate, we possess a deep pipeline of preclinical immuno-oncology compounds. As an example, SL-9258 is designed to inhibit the interaction between TIGIT and its known ligands, including PVR, PVRL2, PVRL3, and NECTIN-4, while simultaneously activating HVEM and LTβ receptors with two preformed LIGHT trimers. With the addition of HVEM and LTβ receptor activation, we believe this compound is a highly differentiated TIGIT inhibitor. Utilizing a proprietary animal model of PD-1 acquired resistance, SL-9258 demonstrated differentiation from antibody-mediated TIGIT blockade in its ability to overcome checkpoint inhibitor acquired resistance.

In addition to our preclinical ARC compounds, we have a pipeline of preclinical GADLEN compounds. The two most advanced compounds from our GADLEN platform are a CD20-directed GADLEN and a B7-H3-directed GADLEN. We have shared *in vitro* preclinical data demonstrating that the CD20-directed GADLEN stimulated human gamma delta T cells to target and kill human CD20 expressing B cells. Additionally, we conducted a non-GLP (as defined below) non-human primate study that demonstrated that the CD20-directed GADLEN was both well tolerated and led to B cell depletion in a dose-dependent manner. The CD20-directed GADLEN may have therapeutic utility in certain autoimmune indications, via depletion of autoantibody producing CD20-positive B-cells. The B7-H3-directed GADLEN may have therapeutic utility in certain solid tumors. We plan to provide additional detail and further guidance on our GADLEN platform in 2023.

In February 2023, following completion of our Phase 1 dose-escalation clinical trial of SL-279252 in patients with advanced solid tumors, and evaluation of the relevant data, we discontinued clinical development of SL-279252. We did not observe an overall response rate necessary to justify continued development in a very difficult PD-1 relapsed/refractory patient population.

Our Platforms

Our ARC Platform

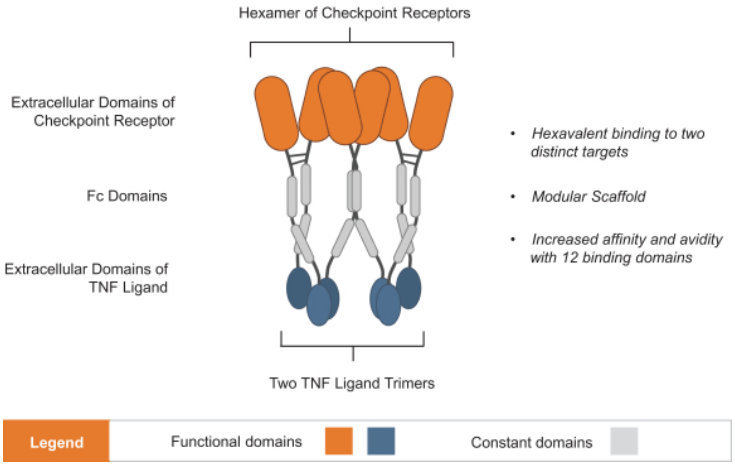
Our proprietary ARC platform has the potential to create therapeutics that can dramatically change the way we treat cancer and other diseases. We developed the ARC platform to address the need for a single therapeutic that consolidates multiple immune functions. Compounds developed from our ARC platform simultaneously block immune checkpoint receptors and activate costimulatory molecules in the tumor necrosis factor, or TNF, superfamily.

The functional domains of ARC compounds are derived from native human proteins, rather than antibody binding domains. This enables the rapid generation of new constructs, given that the starting template for distinct ARC compounds is the human genome. Therefore, an ARC compound can be taken from the conception stage to a manufactured purified protein in approximately six weeks, whereas it can take approximately six months to reach the same stage for an antibody therapeutic candidate. This rapid reduction in discovery processing time, has allowed us to generate more than 400 unique, dual-sided fusion proteins.

Structure of an ARC Compound

Our proprietary ARC platform is designed to overcome the limitations of existing bivalent antibodies. ARC compounds consolidate checkpoint blockade and immune costimulation within a single therapeutic. Additionally, ARC compounds possess a structure that matches the native structure of the target receptors and colocalizes both mechanisms of activity within the immune synapse to promote a coordinated immune response. We designed the ARC platform as a modular scaffold wherein three principal components are fused together, comprising a human Type 1 extracellular domain protein, an optimized, proprietary Fc domain, and a human Type 2 extracellular domain protein. As shown in Figure 1 below, one end of the ARC compound consists of a checkpoint receptor domain and the opposite end consists of a TNF ligand domain, connected by an optimized, proprietary scaffold such as an Fc domain. We designed ARC compounds to self-assemble into a hexameric structure, as shown in Figure 1 below, comprising six distinct checkpoint receptor domains and six distinct TNF ligand domains, which importantly form two trimerized costimulatory ligand domains.

Figure 1—Structural Properties of ARC Compounds



The unique dual-sided structure of our ARC compounds allows us to simultaneously and effectively target a wide array of pathways for the creation of a deep and differentiated product pipeline. We utilize our understanding of disease pathology and immune dysfunction to identify pairings of optimal domains. Initially, our efforts are concentrated on three broad target families: immune checkpoints, TNF superfamily costimulatory receptors, and cytokines.

We believe that the following features represent the key advantages offered by compounds developed with the ARC platform:

- Matching native structure of TNF receptors
- Target specificity, high affinity, and high avidity
- Replacing tumor immune evasion with potent immune stimulation
- Versatility

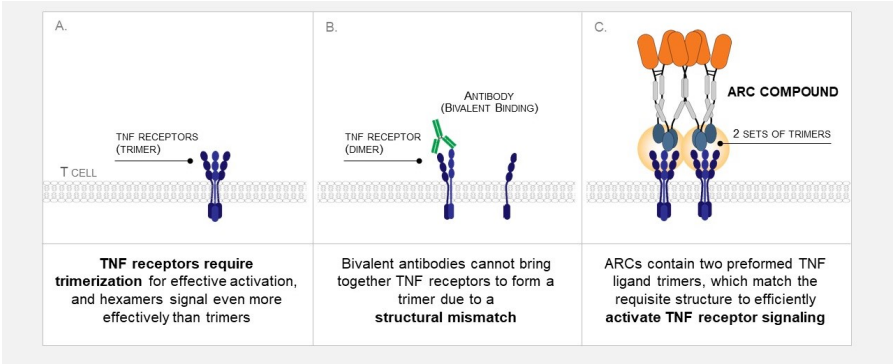
- Speed from concept to compound to clinic
- Accelerated lead selection process

We believe these collective advantages create the potential for the capital-efficient identification and pursuit of differentiated product candidates.

While many TNF receptor agonist antibodies have been developed and tested in human clinical trials, most have been discontinued prior to pivotal studies due to toxicity. As shown in Panel A of Figure 2 below, activation of TNF receptors, such as CD40, and downstream signaling requires the assembly of three receptor molecules, or trimerization. As shown in Panel B of Figure 2 below, there is a structural mismatch between bivalent antibody therapeutics and trimeric TNF receptors. Traditional bivalent antibodies can only bind to two TNF receptors and are thus unable to individually trimerize a TNF receptor, leading to weak signaling of TNF pathways. For TNF receptor agonist antibodies to trimerize a TNF receptor, multiple antibodies must be cross-linked through Fc receptors located on accessory cells. This mechanism becomes less effective at increasing antibody doses due to saturation of TNF receptors and Fc receptors independently of each other. Consequently, there is no free Fc receptor available to cross-link the TNF receptor bound antibody. This effect manifests in clinical trials as an atypical dose-response relationship, known as a "bell-shaped" dose-response curve, wherein any signs of immune activation initially increase with dose but then subsequently decrease at higher doses. As shown in Panel C of Figure 2, ARCs are designed to self-assemble into two sets of TNF trimers, which induces trimerization of TNF receptor targets and drives a costimulatory signal.

We believe that the totality of our clinical data generated to date, from multiple ARC-derived product candidates and across multiple indications, provide strong evidence that our ARC compounds can uniquely activate members of the TNF superfamily by addressing certain structural properties of these receptors. For example, our clinical data demonstrate that high levels of receptor occupancy of CD40 are achievable with an ARC, and that the "bell shaped" dose-response curve observed with antibodies was not seen in humans treated with SL-172154. Instead, we believe that the pharmacodynamic data indicate that SL-172154 may more effectively activate CD40-dependent pharmacodynamic effects in human cancer patients, in a manner that allows this pathway to be appropriately drugged and may provide benefit in the treatment of cancer patients.

Figure 2—Antibody Therapies Lead to Inefficient TNF Pathway Activation



Versatility of the Platform

The modularity of our dual-sided fusion protein platforms, including our ARC platform, facilitates a vast repertoire of potential dual-sided fusion proteins that can be synthesized and developed. In the human genome, there are more than 1,400 Type 1 membrane proteins, which are characterized by an extracellular amino terminal domain, and more than 450 Type 2 membrane proteins, which are characterized by an extracellular carboxy terminal domain. ARC compounds are assembled from any combination of Type 1 and Type 2 membrane proteins and, therefore, have significant diversity, with more than 630,000 possible combinations. Within this vast set of possible combinations, we have chosen to focus initially on three classes of targets that have already shown significant clinical relevance for the treatment of cancer comprising immune checkpoints, the TNF superfamily, and cytokines. We utilize our understanding of disease pathology and immune dysfunction to identify pairings of optimal targets within a single therapeutic.

Our GADLEN Platform

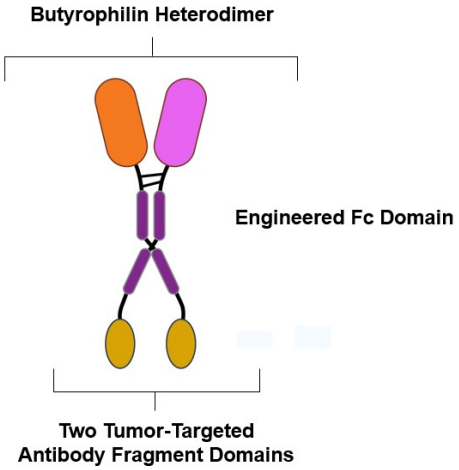
Our expertise in engineering dual-sided, bi-functional fusion proteins has enabled the development of our GADLEN platform, which is designed to leverage gamma delta T cells for the treatment of cancer and autoimmune disorders.

The therapeutic utilization of gamma delta T cells represents an emerging approach for the treatment of cancer. This approach may be particularly beneficial in targeting tumors that are not addressable by alpha beta T cells. Additionally, as immunotherapies that stimulate alpha beta T cell-dependent immune response are increasingly utilized across cancer treatment paradigms, we expect the proportion of patients who will become refractory to alpha beta T cell-mediated therapies will also increase over time, creating an opportunity for therapeutics which harness the antitumor activity of gamma delta T cells.

A majority of T cells in the human body bear an alpha beta T cell receptor, which recognizes tumor antigens presented on major histocompatibility complex, or MHC, molecules. Some cancer cells reduce the expression of MHC molecules or tumor antigens, rendering those cancer cells invisible to most alpha beta T cells. The predominant gamma delta T cell population in the peripheral blood expresses the V gamma 9 / V delta 2 T cell receptor and is activated by a heterodimer consisting of butyrophilin 2A1 and butyrophilin 3A1. Thus, therapeutics which are designed to display a heterodimer of butyrophilin 2A1 and 3A1 may provide a means of modulating gamma delta T cells *in vivo*. We have leveraged our expertise in engineering dual-sided bi-functional fusion proteins to develop a suite of heterodimerized butyrophilin proteins connected to antigen-targeted single chain antibody fragments.

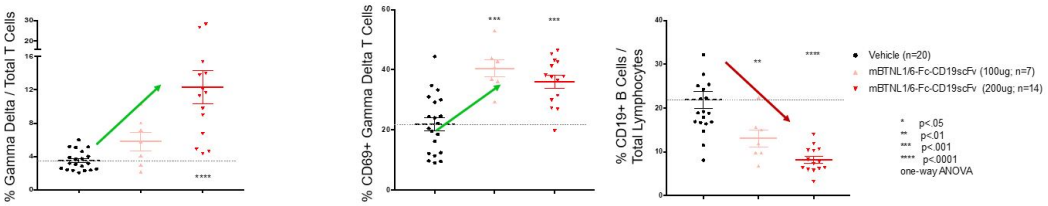
GADLEN compounds are comprised of two distinct fusion protein chains, and an engineered Fc linker domain that facilitates heterodimerization between the two chains. As shown in Figure 3 below, the assembled GADLEN compound contains the extracellular domains of heterodimerized butyrophilin proteins on one side and is linked to tumor antigen specific single chain antibody fragments on the opposite side. The gamma delta T cell receptors recognize and are activated by specific butyrophilin protein heterodimers. Thus, the GADLEN construct is designed to facilitate targeting of specific gamma delta T cells to tumor cells expressing a defined antigen.

Figure 3—GADLEN Platform Overview



To demonstrate the feasibility of the GADLEN approach, a murine GADLEN construct was developed incorporating a butyrophilin 1, or BTNL1, and butyrophilin 6, or BTNL 6, heterodimer and an scFv domain targeting the CD19 antigen. In both mice and humans, gamma delta T cells represent approximately 2% to 5% of the total T cell population, as shown in Figure 4 below, in a murine model. We treated mice on Days 0, 3, and 6 with the murine GADLEN, mBTNL1/6-Fc-CD19scFv. We observed dose-dependent expansion of the endogenous gamma delta T cell compartment to approximately 12% of all T cells 24 hours after the second treatment. Concurrent with expansion, mBTNL1/6-Fc-CD19scFv also caused activation of murine gamma delta T cells, as demonstrated by upregulation of the CD69 activation marker, shown in Figure 4 below. Murine B cells express CD19, and therefore were a potential target of gamma delta T cells following treatment with mBTNL1/6-Fc-CD19scFv. Accordingly, we observed depletion of the endogenous B cell compartment concurrent with gamma delta T cell expansion and activation following treatment with mBTNL1/6-Fc-CD19scFv, as shown in Figure 4 below. Importantly, when mice with established CD19 positive tumors were treated with mBTNL1/6-Fc-CD19scFv, dose-dependent reduction in tumor growth and rejection was observed.

Figure 4—Dose Dependent Gamma T Cell Expansion, Activation, and Killing Activity Following Administration of the GADLEN Compound mBTNL1/6-Fc-CD19scFv



As a result of these data, we have developed multiple human GADLEN compounds. A human GADLEN compound comprising a heterodimer of BTN2A1 and BTN3A1, adjoined via an engineered Fc linker to a CD20 antigen specific scFv domain, was shown in our preclinical model systems to stimulate human gamma delta T cells to target and kill human CD20-expressing B cells in a dose-dependent manner.

We believe that gamma delta T cell engagers may also have a broader therapeutic window than CD3-directed T cell engagers, both because gamma delta T cells represent a smaller proportion of the overall T cell pool in humans, and because gamma delta T cells do not recognize traditional MHC/antigen complexes. To explore this hypothesis, we evaluated the CD20-targeted GADLEN in a non-GLP, dose-range finding and safety study in non-human primates. These data demonstrated that the CD20-targeted GADLEN was well tolerated through at least 25 mg/kg in non-human primates, with no evidence of cytokine release syndrome, and led to rapid and dose-dependent depletion of CD20-expressing B cells within a few hours in non-human primates.

We believe these studies indicate that GADLEN compounds may enable therapeutic modulation of gamma delta T cells *in vivo*, and that GADLEN compounds may be designed to activate tissue-restricted populations of endogenous gamma delta T cells to target specific tumor antigens in both solid and liquid tumors, and with potential therapeutic utility in autoimmune disorders.

We plan to provide additional detail and further guidance in 2023.

Our Strategy

Our goal is to become the world leader in the discovery, development, and commercialization of dual-sided, bi-functional fusion proteins for the treatment of cancer and autoimmune diseases. We plan to achieve this by utilizing our proprietary ARC and GADLEN platforms to create novel therapeutics to treat patients who lack effective treatment options. Key elements of our strategy include:

- Rapidly advancing our clinical-stage ARC product candidate, SL-172154, through clinical development and marketing approval
- Leveraging our ARC and GADLEN platforms to rapidly advance additional product candidates into clinical development
- Continuing to augment our fusion protein manufacturing capabilities
- Collaborating with leading biopharmaceutical companies
- Building on our culture of R&D excellence and continuing to out-innovate ourselves
- Deepening our intellectual property portfolio to continue to protect our platform technologies and product candidates

Our ARC Product Candidate

SL-172154: A Dual CD47/SIRPα Blocking and CD40-Activating ARC Compound

Clinical Data to Date

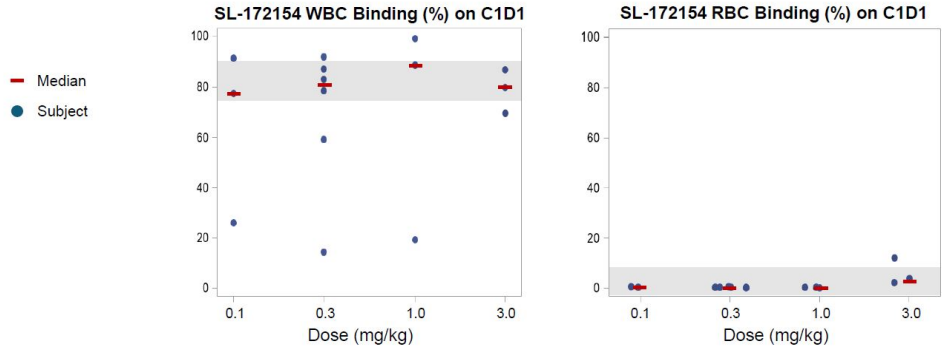
In November 2021, at the SITC Meeting, we presented data from the dose-escalation portion of our completed Phase 1A dose-escalation clinical trial of SL-172154 as monotherapy in heavily pretreated platinum-resistant ovarian cancer patients. As of a September 15, 2021 data cutoff, we had enrolled a total of 15 patients across four dose levels ranging from 0.1 mg/kg to 3 mg/kg. Dose escalation was conducted according to the Modified Toxicity Probability Interval-2 trial design. Patients received SL-172154 on either a weekly schedule or, after doses on day one, day eight, and day 15, a bi-weekly schedule. The patients treated as of September 15, 2021 were heavily pretreated with a median of five prior lines of systemic therapies.

As of October 7, 2021, 14 of the 15 patients treated with SL-172154 in platinum-resistant ovarian cancer had a post-baseline scan at eight weeks and were evaluable for efficacy. Four patients had stable disease as best response including one patient with stable disease of 16 weeks or greater at 0.3 mg/kg and nine had progressive disease.

Subsequently, we completed our Phase 1A monotherapy dose-escalation clinical trial in patients with platinum-resistant ovarian cancer. In this clinical trial, 10 mg/kg was defined as the maximum administered dose, and a maximum tolerated dose was not reached. To date, SL-172154 has been generally well tolerated. We observed a single dose-limiting toxicity of elevated liver enzymes in a single patient at the 10mg/kg dose level. We also frequently observed infusion-related reactions, which are manageable by slowing the rate of infusion and/or by the administration of certain premedication(s). Importantly, however, we have not observed dose-limiting hemolytic anemia, thrombocytopenia or other cytopenias (toxicities which have limited the development of some CD47 inhibitors). We believe that SL-172154 may have a differentiated safety profile, which may be due to the lack of an Fc gamma receptor binding Fc domain.

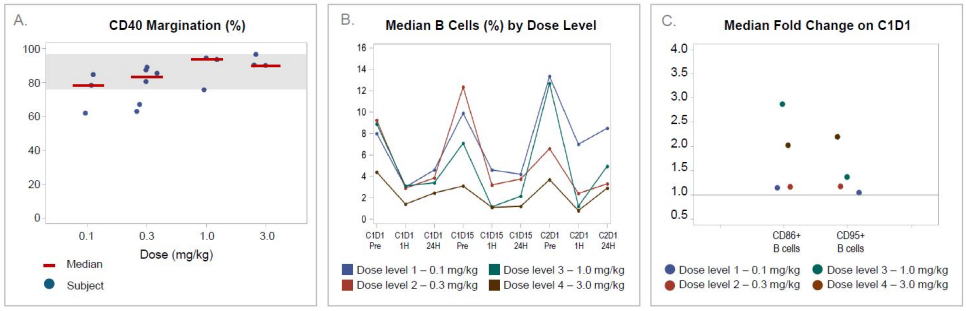
We have observed high levels of target occupancy of SL-172154 on both CD47 and CD40 through 10 mg/kg. As shown in Figure 5, we observed preferential binding of SL-172154 to CD47 positive leukocytes compared to red blood cells. Binding to leukocytes approached near-full CD47 target occupancy at doses greater than 1 mg/kg.

Figure 5—CD47 Targets Occupancy of SL-172154 on White Blood Cells and Red Blood Cells



We have also observed unique pharmacodynamic effects consistent with on-target CD40 activation. Immediately post-infusion of SL-172154, a rapid, dose-dependent margination of CD40 positive B cells from the circulation was observed, as shown in Panel A and Panel B of Figure 6. We also observed an increase in B cell activation markers CD86 and CD95 following each infusion of SL-172154, as shown in Panel C of Figure 6. Additionally, increases in on-target cytokines such as IL-12, CCL2, CCL3, CCL4 and CCL22 have been observed following each infusion of SL-172154. No evidence of a bell-shaped dose response curve was observed through 10 mg/kg, a dose at which high levels of CD40 target occupancy were observed.

Figure 6—CD40 Activation of SL-172154 with Dose-Dependent Margination and Activation B Cells



In paired biopsies collected from our Phase 1A clinical trial in patients with platinum-resistant ovarian cancer, we have observed increases in CD68 positive macrophages as well as both CD40 and MHC Class II activation markers in the tumor microenvironment, consistent with induction of an innate immune response. Additionally, we have seen an increase in PD-L1 expression by the combined positive score, suggesting that the increase in tumor-infiltrating CD8 positive T cells induced a

local interferon response. We have also observed increases in Ki67 positive CD8 T cells and the Granzyme B positive CD8 T cells. These findings are consistent with the postulated mechanism of action of SL-172154: simultaneous CD47 inhibition and CD40 activation bridging an innate to adaptive immune response.

Clinical Development Strategy

We believe that SL-172154 is a highly differentiated CD47 inhibitor with potential for both best-in-class and first-in-class development opportunities. We are conducting Phase 1 clinical trials evaluating the administration of SL-172154 in both solid tumors and hematologic malignancies. As a class, CD47 inhibitors are being developed in combination with other agents that potentiate phagocytosis and initiate an immune response, such as chemotherapy, ADCP-competent antibodies, antibody drug conjugates, and others.

Ovarian Cancer

Ovarian cancer expresses the highest levels of CD47 of any solid tumor and is a tumor type with a significant infiltration of macrophages, which express CD40. We believe this makes ovarian cancer particularly well-suited to the investigation of SL-172154. We are conducting a Phase 1 clinical trial of SL-172154 administered intravenously in patients with advanced ovarian, fallopian tube, and primary peritoneal cancers, collectively referred to as ovarian cancer. Patients that are eligible for this trial have relapsed after standard-of-care therapies and are ineligible for further platinum-based therapies. The primary objective of this trial is to assess the safety and tolerability of SL-172154. The secondary objectives include evaluation of the pharmacokinetic and pharmacodynamic profiles and the antitumor activity of SL-172154.

We have completed our Phase 1A monotherapy dose-escalation clinical trial in patients with platinum-resistant ovarian cancer. In this clinical trial, we reached a maximum administered dose of 10 mg/kg. We did not reach a maximum tolerated dose. We are evaluating SL-172154 in a Phase 1B combination dose-escalation and dose-expansion clinical trial in platinum-resistant ovarian cancer in combination with liposomal doxorubicin. We have selected a starting dose of 3 mg/kg of SL-172154 in this trial. Our protocol allows for further dose escalation in the combination, if warranted. Liposomal doxorubicin is a standard-of-care chemotherapy for this patient population. According to the literature, liposomal doxorubicin upregulates calreticulin, an endogenous "eat me" signal, on the surface of tumor cells. Consequently, we believe that liposomal doxorubicin is an attractive combination partner due to upregulation of calreticulin and induction of immunogenic cell death. In *in vivo* preclinical studies, we observed improved anti-tumor activity with the combination of liposomal doxorubicin and SL-172154 compared to liposomal doxorubicin alone or SL-172154 alone. Furthermore, because the overall response rate of this patient population to liposomal doxorubicin is approximately 10%, there is significant opportunity for improved response rates in combination with SL-172154, wherein we believe the contribution of SL-172154 will be discernible.

In addition to our combination strategy of SL-172154 in combination with liposomal doxorubicin, we are evaluating SL-172154 in a Phase 1B combination dose-escalation and dose-expansion clinical trial in platinum-resistant ovarian cancer in combination with mirvetuximab soravtansine, marketed by ImmunoGen, Inc, or ImmunoGen. Mirvetuximab soravtansine is an antibody-drug conjugate targeting folate receptor alpha, or FRα, which provides for both direct tumor cell killing as well as enhanced macrophage phagocytosis through binding with Fc gamma receptors, and has received accelerated approval for platinum-resistant ovarian cancer patients whose tumors are shown to be FRα positive, defined as ≥75%, as determined by the VENTANA FOLR1 (FOLR1-2.1) Assay, using the PS2+ scoring method. Pre-clinical studies have shown that both of these mechanisms may be complementary to the mechanism of SL-172154 by enhancing the activity of macrophages to phagocytose FRα- expressing ovarian cancer cells, and that SL-172154 may broaden the activity of mirvetuximab soravtansine, particularly for patients with tumors that express lower levels of FRα.

We intend to enroll patients with broader FRα expression, including those with "high" (greater than ≥75% of tumor cells staining with 2+ intensity), "medium" (≥50% to <75% of tumor cells staining with 2+ intensity), and "low" (≥25% to <50% of tumor cells staining with 2+ intensity) expression of FRα, as determined by the VENTANA FOLR1 (FOLR1-2.1) Assay, using the PS2+ scoring method. Based on our preclinical data, we believe that the addition of SL-172154 to mirvetuximab soravtansine will increase responses rates in the "medium" and "low" expressors of FRα and/or potentially provide a more durable response across the entire spectrum of FRα expressors.

We expect to announce complete data from the Phase 1A monotherapy dose-escalation trial and initial data from the Phase 1B combination clinical trial with liposomal doxorubicin midyear 2023. Additionally, we expect to announce initial data from the Phase 1B combination clinical trial with mirvetuximab soravtansine in the second half of 2023.

Acute Myeloid Leukemia and Higher-Risk Myelodysplastic Syndrome

We are conducting a Phase 1A/B clinical trial for SL-172154 in patients with AML and HR-MDS. This ongoing Phase 1 clinical trial will evaluate the safety, tolerability, pharmacokinetics, antitumor activity, and pharmacodynamic effects of SL-172154, as both monotherapy and in combination. In AML, we plan to evaluate SL-172154 in combination with both

azacitidine and venetoclax. In both HR-MDS and TP53 mutant AML, we plan to evaluate SL-172154 in combination with azacitidine.

We are conducting the Phase 1B dose-escalation portion of this trial of SL-172154 in combination with azacitidine in a parallel staggered manner. Monotherapy dose-escalation and initial dose-escalation combination cohorts are anticipated to be in a heavily pretreated, predominantly refractory patient population. Once a recommended dose and schedule have been determined in combination with azacitidine, we plan to enroll patients in expansion cohorts in combination with azacitidine, with or without venetoclax, depending on the indication.

As a class, CD47 inhibitors have demonstrated clinical activity in both AML and HR-MDS, in combination with these standard-of-care chemotherapies that provide the requisite "eat me" signals. We see an opportunity for SL-172154 to continue to differentiate from other compounds in the field due to the combined effects of CD47 blockade and CD40 costimulation. Specifically, we believe that our preclinical and initial clinical data from our Phase 1A clinical trial in ovarian cancer indicate that SL-172154 may differentiate from other CD47/SIRPα inhibitors in one or more of the following ways:

- Improved overall response rate due to CD40-mediated activation of both innate and adaptive immunity
- Improved response durability due to enhanced CD40-mediated activation of adaptive immunity
- Differentiated safety profile due to the absence of dose-limiting anemia or thrombocytopenia

We expect to announce initial data, as monotherapy and in combination, from the dose-escalation portion of this Phase 1A/B trial in the first half of 2023.

Following the COVID-19 pandemic, we have experienced delays in our clinical trials of SL-172154. In particular, we have experienced: delays with certain third-party vendors supporting this trial, including third-party manufacturers; difficulty procuring sufficient quantities of raw materials required for our manufacturing processes; and staffing shortages at many clinical trial sites. We expect to continue to experience some or all of these delays in the future.

Preclinical Experience

Our lead product candidate, SL-172154, simultaneously inhibits CD47 and activates the CD40 receptor. The pairing of a CD40 agonist domain to a CD47 inhibitory domain was selected based on prior publications which demonstrated that tumor rejection in the setting of CD47 inhibition was dependent upon a T cell mediated adaptive immune response. Agents which only block the interaction between CD47 and SIRPα do not directly activate T cell mediated adaptive immunity, but instead function to enable macrophage mediated phagocytosis of tumor cells. Antigen presenting cells, including macrophages, express CD40. Stimulation of CD40 on antigen presenting cells is known to improve the efficiency of antigen presentation and activation of T cell mediated adaptive immunity, including antitumor immunity.

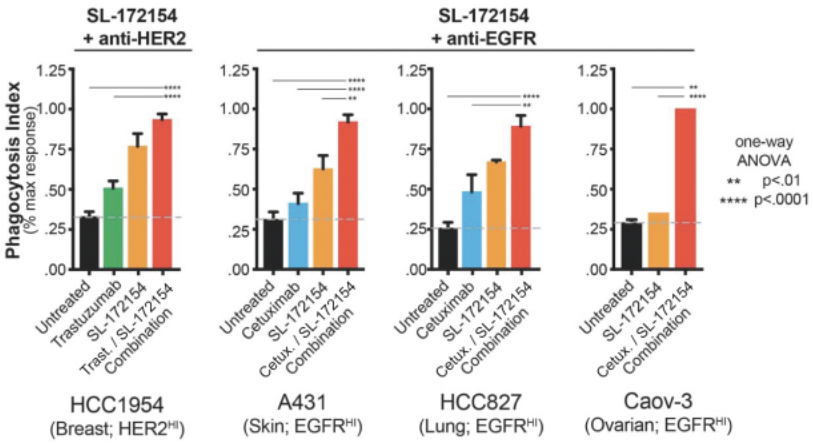
To date, we have conducted extensive preclinical studies of SL-172154 that have demonstrated the following:

- Specific binding to CD47 and CD40 with high picomolar affinity
- A significant increase in macrophage-mediated phagocytosis of tumor cells
- Durable receptor occupancy to CD47 expressing cells
- Dose-dependent CD40-mediated pharmacodynamic activity
- The activation of antigen presenting cells by a CD40-induced type I interferon response
- Dose-dependent increases in multiple anti-cancer cytokines in both non-human primates and by human lymphocytes
- Dose-dependent activation of a CD8 positive T cell response, which was responsible for tumor cell killing
- Superior tumor rejection as compared to CD47 inhibitory antibodies, CD40 agonist antibodies, or the combination thereof, in mouse tumor models

Taken together, we believe these data demonstrate the potential ability of SL-172154 to activate and bridge the adaptive and innate immune responses.

We performed standard *in vitro* tumor cell phagocytosis assays to demonstrate whether SL-172154 enhanced macrophage-mediated phagocytosis of various tumor cell lines, both alone and in combination with tumor-targeted ADCP-competent antibodies. As shown in Figure 7 below, consistent with the mechanism of action of CD47 blocking agents, SL-172154 significantly enhanced the ability of macrophages to phagocytose tumor cells in the presence of tumor-targeted ADCP-competent antibodies. Additionally, SL-172154 potentiated macrophage-mediated phagocytosis of tumor cells that expressed calreticulin, a well-established "eat me" signal expressed on the surface of cells marked for phagocytosis.

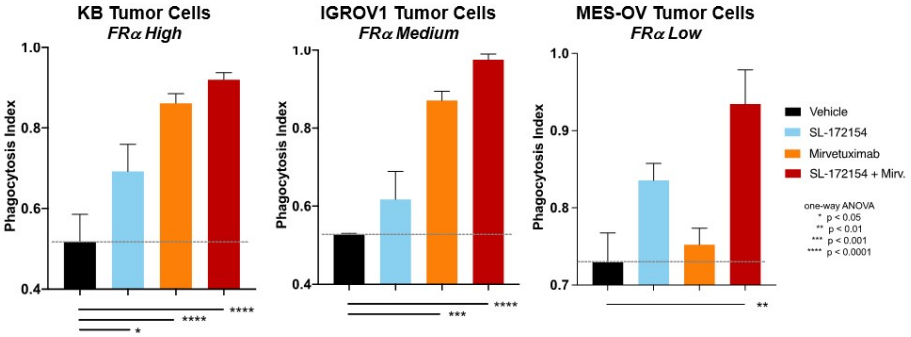
Figure 7—Tumor Phagocytosis Activity of SIRPα-Fc-CD40L with or without ADCP-competent Antibodies



Human monocyte derived macrophages were co-cultured with HCC1954, A431, HCC827, or Caov-3 cells in the presence of an IgG negative control, SL-172154, an ADCP-competent tumor-targeted antibody, including Trastuzumab or Cetuximab, or the combination of SL-172154 and the ADCP-competent tumor-targeted antibody. After two hours, the proportion of tumor cells phagocytosed by human macrophages was determined and reported as the phagocytosis index.

We also performed standard *in vitro* tumor cell phagocytosis assays to demonstrate whether SL-172154 enhanced macrophage-mediated phagocytosis across a range of tumor cells expressing varying levels of FRα expression, both alone and in combination with mirvetuximab soravtansine, an antibody drug conjugate, or ADC, composed of a FRα-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin-targeting agent, designed to kill the targeted cancer cells. As shown in Figure 8 below, consistent with the mechanism of action of CD47 blocking agents, SL-172154 significantly enhanced the ability of macrophages to phagocytose tumor cells in the presence of mirvetuximab soravtansine.

Figure 8—In Vitro Tumor Phagocytosis Activity of SIRPα-Fc-CD40L with or without Mirvetuximab Soravtansine



Ovarian cancer cells KB, IGROV1, or MES-OV, that express varying levels of cell surface FRα were cultured with human monocyte derived macrophages in the presence of a vehicle control, SL-172154, mirvetuximab soravtansine, or the combination of SL-172154 and mirvetuximab soravtansine. After treatment, the proportion of tumor cells phagocytosed by human macrophages was determined and reported as the phagocytosis index.

Collaboration and License Agreements

Collaboration Agreement with Takeda

On August 8, 2017, we entered into a collaboration agreement with Millennium Pharmaceuticals, Inc., or Takeda, a wholly-owned subsidiary of Takeda Pharmaceutical Company, Ltd., or the Collaboration Agreement. The Collaboration

Agreement was mutually terminated pursuant to the termination agreement, or the Termination Agreement, dated November 8, 2021. Under the terms of the Termination Agreement, we are not required to satisfy any remaining performance obligations, we will not make any payments to or receive any future milestone or royalty payments from Takeda, and all options to license and rights of first negotiation held by Takeda under the Collaboration Agreement were terminated.

Clinical Trial Collaboration and Supply Agreement with ImmunoGen

On February 4, 2022, we entered into a Clinical Trial Collaboration and Supply Agreement, or the Clinical Trial Collaboration Agreement, with ImmunoGen. Pursuant to the Clinical Trial Collaboration Agreement, ImmunoGen will supply us with a sufficient quantity of mirvetuximab soravtansine for use in our Phase 1B combination cohort evaluating SL-172154 in combination with mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer, or the Study. We will bear all other costs associated with the conduct of the Study, except that ImmunoGen will reimburse us for $2.0 million of the costs we incur. We have sole authority over the design, conduct, and control of the Study. We will provide ImmunoGen with a final study report, or the Final Study Report, relating to the Study promptly following completion thereof.

Unless sooner terminated, the term of the Clinical Trial Collaboration Agreement continues until the delivery of the Final Study Report. We may terminate earlier upon 60 days' written notice for any reason; provided, that if the Study is underway at the time of such notice, such termination will only be effective 60 days following the parties' mutual agreement on a written plan for the winddown or termination of the Study. ImmunoGen may terminate earlier if it believes, in good faith, that mirvetuximab soravtansine is being used in the Study in an unsafe manner or that the Study may unreasonably affect patient safety. In addition, either party may terminate the agreement due to a material breach by the other party (subject to a cure period), if either party determines in good faith, based on a review of the clinical data or other information, that the Study poses imminent danger to patients, if a regulatory authority takes any action that causes it to be unreasonable for, or otherwise prevents, the terminating party from supplying its compound for the Study, or if a party withdraws any applicable regulatory approval for its compound or discontinues development of its compound for any reason.

Nighthawk License Agreement

In June 2016, we entered into an Exclusive License Agreement, or the Nighthawk License Agreement, with Nighthawk Biosciences, Inc. (f/k/a Heat Biologics Inc.), or Nighthawk. The Nighthawk License Agreement was subsequently amended in November 2016, December 2016, and March 2017. Pursuant to the Nighthawk License Agreement, Nighthawk granted to us (1) a worldwide, sublicensable exclusive license to research, develop, manufacture, and commercialize products under three provisional patent applications, including all patents issuing from such applications, or the Fusion Protein Patent Rights, and (2) a worldwide, sublicensable nonexclusive license to research, develop, manufacture, and commercialize certain know-how owned and controlled by Nighthawk related to the Fusion Protein Patent Rights.

Under the Nighthawk License Agreement, Nighthawk was required to conduct certain research and development services under a mutually-agreed upon research and development plan and Nighthawk was eligible to receive financial support from us for these efforts. Effective March 2017, Nighthawk completed all research and development services under the Nighthawk License Agreement and assigned to us three patent applications and all data derived from the research and development activities, referred to collectively as the Research Services Inventions. Pursuant to the terms of the Nighthawk License Agreement, we are obligated to use commercially reasonable efforts to diligently research and develop at least one product covered by the Fusion Protein Patent Rights, including the obligation to file an Investigational New Drug, or IND, application for such product. Our development efforts to date, including the development of SL-279252 and certain other ARC compounds, satisfy these obligations. In addition, we are to provide annual reports to Nighthawk on or before the anniversary of the effective date of the Nighthawk License Agreement to inform Nighthawk of our progress.

Unless sooner terminated or extended, the term of the Nighthawk License Agreement continues until the later of (1) 20 years following the effective date, and (2) the expiration of the last-to-expire royalty term. Either party may terminate the agreement due to a material breach by the other party (subject to a 90-day cure period) or if the other party files for bankruptcy. In the event we terminate the Nighthawk License Agreement due to a material breach by Nighthawk, Nighthawk must assign to us all right, title, and interest in the patent rights licensed under the Nighthawk License Agreement.

In addition to an upfront payment of $50,000, which we made in 2016, the Nighthawk License Agreement requires us to make further payments to Nighthawk in the future of up to $20.6 million in the aggregate for the achievement of specified development, regulatory, and commercial sale milestones for certain licensed products. We are also required to pay Nighthawk a percentage of certain upfront fees or other non-royalty payments that are not tied to milestone events which we receive in connection with certain sublicenses of the Fusion Protein Patent Rights. We are also required to pay Nighthawk a royalty on all worldwide net sales by us, our affiliates, and sublicenses of certain licensed products in the low single digits. Royalties are payable, on a product-by-product and country-by-country basis, commencing on the first commercial sale of such product and continuing until the last-to-expire valid patent claim to the licensed patent rights that cover such product in that country.

Manufacturing and Supply

By working with third-party vendors to conduct activities in compliance with current Good Manufacturing Practices, or cGMP, we have invested significant resources to identify and scale up a suitable manufacturing process for our product candidates and ARC compounds, including SL-172154. Currently, ARC compounds are produced by mammalian cell lines commonly used in the manufacture of monoclonal antibodies, including Chinese hamster ovary, or CHO, cells. SL-172154 has achieved cell culture titer greater than two grams per liter, and another ARC compound has achieved titers exceeding seven grams per liter. Purification of ARC compounds initially utilizes affinity chromatography directed to the Fc domain for capture, and subsequent chromatography steps are designed to remove process-related impurities including CHO derived DNA and proteins.

To date, we have manufactured bulk drug substance, or BDS, for our product candidates utilizing the services of a limited number of third-party contract manufacturers, with whom we maintain master service agreements, pursuant to which we may manufacture BDS on a per project basis. We may terminate the master services agreements at any time for convenience in accordance with the terms of the agreement. These contract manufacturers, or we, may also terminate the master services agreements with respect to an uncured breach by the other party in accordance with the terms of the agreement. These agreements include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

Given the complexity of manufacturing our dual-sided, bi-functional fusion proteins, our increased need for manufacturing driven by multiple clinical trial programs, and the challenges faced by biologics manufacturing facilities during the COVID-19 pandemic, we work to ensure that we have arrangements with multiple contract manufacturers to reduce the risk of single-source procurement of BDS. Additionally, we built an in-house facility to support our cell line development, manufacturing process development, analytical assay development, and non-GMP manufacturing activities.

We expect to continue to devote significant resources to process development and optimization of the manufacture of our product candidates. To our knowledge, no other company has successfully scaled up commercial manufacturing of dual-sided, bi-functional fusion proteins. Due to the novelty of our product candidates, we may face challenges in developing large-scale manufacturing processes. Moreover, the nature of biologic medicines could create challenges for the stability of the drug substance. While these and other challenges may result in timeline delays and higher costs, we believe that we will have sufficient BDS to support our current clinical trial programs.

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 cancer therapies. 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 cancer therapies. There are many other companies that have commercialized or are developing cancer therapies, including large pharmaceutical and biotechnology companies, such as AstraZeneca/MedImmune, Bristol Myers Squibb, Merck, Novartis, Pfizer, Roche/Genentech and Gilead.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (e.g., T cell engagers), adoptive cellular therapies (e.g., CAR-Ts), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin, and targeted cancer vaccines.

With respect to our lead product candidate, SL-172154, we are aware of other competing clinical-stage therapeutics that target the CD47 pathway or the CD40 pathway, which include, but are not limited to magrolimab, evorpacept, lemzoparlimab TTI-621, TTI-622, DSP107, and APX005M.

With respect to our second proprietary platform, the GADLEN platform, we are aware of potentially competing efforts to develop compounds to utilize gamma delta t cells through various modalities for the treatment of certain cancer indications, including, but not limited to, efforts by Adicet Bio, Gamma Delta Therapeutics, ImCheck Therapeutics, and Lava Therapeutics.

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 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 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, or the Hatch-Waxman Act, 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 United States Patent and Trademark Office 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.

Intellectual property related to our most advanced programs is summarized below. We generally file patent applications directed to our key technologies and programs in an effort to secure our intellectual property positions. As of January 17, 2023, we own or exclusively license (i) more than 20 patents and more than 15 pending non-provisional patent applications in the United States and (ii) 10 patents and more than 120 pending patent applications in jurisdictions outside of the United States. We also own additional pending provisional patent applications in the United States and pending international patent applications filed under the Patent Cooperation Treaty, or PCT. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office and other patent offices may be significantly revised before issuance, if granted at all.

SL-172154 Product Candidate

As of January 17, 2023, we own or exclusively license (i) 5 patents and 5 pending non-provisional patent applications in the United States and (ii) 7 patents and more than 25 pending patent applications in jurisdictions outside of the United States (including, among others, Australia, Canada, China, Europe, and Japan) that relate to SL-172154.

These patents and applications originate from several different patent families. Patents granted in a family generally directed to compositions and methods of treating cancer are expected to expire in the United States in 2036, without taking potential patent term extension or patent term adjustment into account. Patents granted in other families, generally directed to methods of treating cancer with various combination agents, are expected to expire in the United States in 2038 and 2039, depending on the family and without taking potential term extension or patent term adjustment into account. The terms of individual patents granted in jurisdictions outside of the United States depends on the legal term for patents in those jurisdictions.

ARC Platform

As of January 17, 2023, we own or exclusively license (i) more than 15 patents and 15 pending non-provisional patent applications in the United States and (ii) 10 patents and more than 100 pending patent applications in jurisdictions outside of the United States (including, among others, Australia, Canada, China, Europe, and Japan) that relate to the ARC platform. These include patents and/or patent applications related to SL-172154 and other ARC compounds combining TIM3, PD-1, SIRPα, TIGIT, CSF1R, VSIG8, or FLT3L with OX40, CD40L, 4-1BBL, or LIGHT.

These patents and applications originate from several different patent families. Patents granted in families generally directed to compositions and methods of treating cancer are expected to expire in the United States in 2036, 2038, 2039, and 2040, depending on the family and without taking potential patent term extension or patent term adjustment into account. Patents granted in other families, generally directed to methods of treating cancer with various combination agents, are expected to expire in the United States in 2038, 2039, and 2040, depending on the family and without taking potential patent term extension or patent term adjustment into account. The terms of individual patents granted in jurisdictions outside of the United States depends on the legal term for patents in those jurisdictions.

GADLEN Platform

As of January 17, 2023, we (i) own 2 patents and 2 pending non-provisional patent application in the United States and (ii) more than 10 pending patent applications in jurisdictions outside of the United States (including, among others, Australia, Canada, China, Europe, and Japan) that relate to the GADLEN platform.

These patents and applications originate from a family generally directed to compositions and methods of treating cancer. Patents granted in this family are expected to expire in the United States in 2040, without taking potential patent term extension or adjustment into account.

Trademark Protection

As of February 3, 2023, we own a registered trademark and an allowed application for "ARC" and an allowed application for "GADLEN" with the U.S. Patent and Trademark Office. We plan to register trademarks in connection with our biological products.

Licensed Intellectual Property from Nighthawk Biosciences, Inc.

In June 2016, we entered into an exclusive license agreement with Nighthawk, pursuant to which we received an exclusive (as to the patent rights), non-transferable, sublicensable, worldwide, royalty-bearing, non-field restricted license to certain patent rights and know-how, including rights related to the ARC platform. We paid Nighthawk an initial license fee of $50,000, and we are obligated to pay Nighthawk fees upon receipt of certain sublicensing income, achievement of certain milestones, and royalties upon sales of commercial products. The Nighthawk license provides us rights in the patent family including PCT/US16/54598. As of January 17, 2023, that family includes (i) 11 patents and 2 pending non-provisional patent applications in the United States, and (ii) 7 patents and more than 25 pending applications in jurisdictions outside of the United States (including, among others, Australia, Canada, China, Europe, and Japan). We control prosecution, maintenance, and enforcement of this family of patents and patent applications.

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.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and other federal, state, local, and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, 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, or 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, or 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, or 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 the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol 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. 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, or 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.

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, or 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, or PSP, 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.

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, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require

one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

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 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.

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 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).

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. 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, or RMAT, designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century 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. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under 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.

Fast track designation, breakthrough therapy designation, priority review and RMAT designation 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. In May 2018, the Right to Try Act established a new regulatory pathway to increase access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial.

The Consolidated Appropriations Act, 2023 strengthens the FDA's authority to require and regulate post-approval studies of accelerated approval drugs and to expedite the rescission of accelerated approval based on these post-approval studies.

Orphan Drug Designation

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease 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 biologic 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 or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug 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 designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which 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.

Regulation of Diagnostic Tests

Our drug candidates may require use of a diagnostic to identify appropriate patient populations for our product candidates. These diagnostics, often referred to as companion diagnostics, are medical devices, often *in vitro* devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. We expect that any companion diagnostic developed for our drug candidates will utilize the PMA pathway.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance, for novel drugs such as our drug candidates, a companion diagnostic device and its corresponding drug should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are 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. In September 2021, the FDA issued two 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 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. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. 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. As of March 2020, certain products previously approved as drugs under the FDCA, such as insulin and human growth hormone, are now deemed to be biologics under the PHSA, which means they may face competition through the biosimilars pathway and are not be eligible for the twelve-year period of exclusivity granted to new BLAs. 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, or IRA, is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

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, or AKS; the federal False Claims Act, or FCA; 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 activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. 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. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. 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.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, 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. The FCA imposes mandatory treble damages and per-violation civil penalties up to approximately $25,000.

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 CMS information related to payments or other transfers of value made 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 Open Payments.

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 could apply to our operations or the operations of our partners. For example, HIPAA, as amended by HITECH, and their respective implementing regulations imposes 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 that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable health information for or on behalf of such covered entities. 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. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the FTC, 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.

In addition, state laws govern the privacy and security of personal information, including health-related information, in certain circumstances. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the CCPA, which went into effect on January 1, 2020, creates new data privacy obligations for covered companies and provides new privacy rights to California residents.

Coverage and Reimbursement

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.

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. These price negotiations will begin in 2023. The IRA also provides a new "inflation rebate" covering Medicare patients that will take effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision will require 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.

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 legislative 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.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of 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 through 2030 with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, 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.

Notwithstanding the Inflation Reduction Act, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators 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.

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 collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679, or GDPR, which came into force in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the

ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes 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 notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to 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 EU/EEA that are not considered by the EC to provide an adequate level of data protection (including the United States). 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, or SCCs. On March 25, 2022, the EC and the United States announced that they have agreed in principle on a new Trans-Atlantic Data Privacy Framework. Following this statement, on October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Signals Intelligence Activities', which implemented the agreement in principle. On that basis, the EC prepared a draft adequacy decision and launched its adoption procedure. While this new EU-U.S. privacy framework is expected to enter into force in 2023, there is still some uncertainty around the new framework.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) 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 EU Member States 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 EU. Guidance developed at both the EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised.

Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU CTR, 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. The uncertainty regarding the interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

With regard to the transfer of data from the EU to the United Kingdom, or UK, personal data may now freely flow from the EU to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions include a 'sunset clause' which entails that the decisions will automatically expire four years after their entry into force. Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the GDPR, as incorporated into UK national law), the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization for human medicines in the European 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 EU Clinical Trials Regulation (EU) No. 536/2014, or 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 former regime, which will expire after a transition period of one or three years, respectively, as outlined below in more detail, before a clinical trial can be initiated it must be approved in each EU member state where there is a site at which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority, or NCA, and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU member state before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. 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 NCA and to the Ethics Committees of the EU member state where they occur.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal. 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. The CTR foresees a three-year transition period. EU Member States will work in CTIS immediately after the system has gone live. On January 31, 2023, submission of initial clinical trial applications via CTIS became mandatory, and by January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS.

Under both the former regime and the new CTR, national laws, regulations, and the applicable Good Clinical Practice, or GCP, and Good Laboratory Practice 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, or ICH, guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki.

During the development of a medicinal product, the European Medical Agency, or 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, or CHMP, on the recommendation of the Scientific Advice Working Party, or SAWP. 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, or MAA, of the product concerned.

Drug Marketing Authorization

In the European Union, medicinal products, including advanced therapy medicinal products, or ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union 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 the ATMP Regulation, the Committee on Advanced Therapies, or 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 manufacturing and control information that should be submitted in a In the EU and in Iceland, Norway and Liechtenstein (together the European Economic Area, or EEA), after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a Marketing Authorization, or MA. To obtain an MA of a drug under European Union regulatory systems, an applicant can submit an Marketing Authorization Application, or MAA, through, amongst others, a centralized or decentralized procedure.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the European Commission, or EC, following the scientific assessment of the application by the European Medicines Agency, or EMA, that is valid for all EU Member States as well as in the three additional EEA Member States. 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, or ATMP, and medicinal products with a new active substance indicated for the treatment of certain diseases (AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune 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 marketing authorization through the centralized procedure.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or CHMP, established at the EMA, 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 marketing

authorization. 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 marketing authorization (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 marketing authorization 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, or 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. RMPs and Periodic Safety Update Reports, or PSURs, are routinely available to third parties requesting access, subject to limited redactions.

MA Validity Period

Marketing Authorizations 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.

Additionally, 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. A conditional MA must be renewed annually.

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. New Chemical Entities, or 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 European Union'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.

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union 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 European Union (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 European Union 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 marketing authorization, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for marketing authorization of the medicinal product is submitted. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization 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 marketing authorization.

The EMA's Committee for Orphan Medicinal Products, or COMP, reassesses the orphan drug designation of a product in parallel with the review for a marketing authorization; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of marketing authorization review by the EMA and approval by the EC. Additionally, any marketing authorization 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 marketing authorization, 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 marketing authorization, accept an application to extend an existing marketing authorization or grant marketing authorization 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, or SmPC, addressing the pediatric

population and completed in accordance with a fully compliant Pediatric Investigation Plan, or 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 marketing authorization may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

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, or PDCO. 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 marketing authorization, or 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.

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, or 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 marketing authorization application 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 marketing authorizations. 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 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 European Union 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, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice, or 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 European Union with the intention to import the active pharmaceutical ingredients into the European Union. Similarly, the distribution of pharmaceutical products into and within the European Union 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 European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

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 marketing authorization 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 European Union 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.

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 European Union. 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.

Other Markets

The UK formally left the EU on January 31, 2020 and the transition period, during which EU laws continued to apply to the UK, expired on December 31, 2020. This means EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland. Following the end of the transition period, the EU and the UK concluded the TCA, which applied provisionally from January 1, 2021 and entered into force on May 1, 2021.

The TCA includes provisions affecting the life sciences sector (including on customs and tariffs) but areas for further discussion between the EU and the UK remain. Some specific provisions concerning pharmaceuticals are in place, including the mutual recognition of Good Manufacturing Practice, or GMP, and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

Since January 1, 2021, the EU laws which have been transposed into UK law through secondary legislation continue to be applicable in the UK as "retained EU law." As there is no general power to amend these regulations, the UK government has enacted the Medicines and Medical Devices Act 2021. The purpose of the act is to enable the existing regulatory frameworks in relation to human medicines, clinical trials of human medicines, veterinary medicines and medical devices to be updated. The powers under the act may only be exercised in relation to specified matters and must safeguard public health.

Specified provisions of the Medicines and Medical Devices Act 2021 entered into force on February 11, 2021. The remaining provisions came into effect within two months of February 11, 2021 or will otherwise come into effect as stipulated in subsequent statutory instruments. The Medicines and Medical Devices Act 2021 supplements the UK Medical Devices Regulations 2002, or the UK Regulations, which are based on the EU Medical Devices Directive as amended to reflect the UK's post-Brexit regulatory regime. Notably, the UK Regulations do not include any of the revisions that have been made by the EU Medical Devices Regulation (EU) 2017/745, which, since May 26, 2021, now applies in all EU Member States.

The UK's Medicines and Healthcare products Regulatory Agency, or MHRA, conducted a comprehensive consultation between September and November 2021 on proposals to develop a new UK regime for medical devices in the UK. The proposals include more closely aligning definitions for medical devices and *in vitro* medical devices with internationally recognized definitions and changing the classification of medical devices according to levels or risk. The proposals are intended to improve patient and public safety and increase the appeal of the UK market. The new regime is planned to come into force on July 1, 2023, which will align with the date from which the UK is due to stop accepting CE marked medical devices and require UK Conformity Assessed marking. It is envisaged that, in Northern Ireland, the amended regime could run in parallel with any existing or future EU rules in accordance with the Protocol on Ireland and Northern Ireland.

For other countries outside of the European Union, 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.

Human Capital Management

Shattuck Employees

As of December 31, 2022, Shattuck employed 105 full-time employees at two locations in the United States in Austin, TX and Durham, NC. During 2022, we expanded our capabilities across the two sites by hiring 34 new employees. These employees were hired to support our clinical development, preclinical research and development, and efforts associated with operating as a public company.

We may continue to hire additional employees in 2023 and beyond with a focus on increasing expertise and bandwidth in preclinical and clinical research and development and in-house process development and manufacturing. The Company continually evaluates business needs and opportunities, with a hiring philosophy that balances 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, Shattuck offers 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 comprehensive 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 Shattuck's employees have obtained advanced degrees in their professions. Shattuck supports our employees' further development with individualized development plans, mentoring, coaching, group training and conference attendance.

Research and Development

Research and development expenses for the years ended December 31, 2022 and 2021 were $82.9 million and $56.6 million, respectively.

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 27709 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, 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 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 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.

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 and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We will require additional funding in order to complete development of our product candidates 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, our efforts to access manufacturing capacity, and our 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.
- 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.
- Our compounds, including those from our ARC and GADLEN platforms, are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. We may not be successful in our efforts to use and expand our technology platforms to develop and commercialize our compounds and product candidates, or may experience significant delays in doing so.
- 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.
- Interim, topline, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- Clinical drug development is a lengthy and expensive process with uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and, therefore, be unable to commercialize our product candidates on a timely basis or at all.
- 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 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 product candidates from our ARC and GADLEN platforms, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those product candidates.

Risks Related to Our Business

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 and may never achieve or maintain profitability.

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, 2022 and 2021, we reported a net loss of $101.9 million and $45.0 million, respectively. As of December 31, 2022, we had an accumulated deficit of $219.0 million. We expect to continue to incur significant operating losses for the foreseeable future. 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.

Our limited operating history 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 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.

We will require additional funding in order to complete development of our product candidates 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 investments will enable us to fund our operating expenses into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, 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" offerings, or 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, which could materially and adversely impact our ability to conduct our business.

Our compounds, including those from our ARC and GADLEN platforms, are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. We may not be successful in our

efforts to use and expand our technology platforms to develop and commercialize our current and future product candidates, or may experience significant delays in doing so.

A key element of our strategy is to use and expand our proprietary technologies, including our ARC and GADLEN platforms, to build a pipeline of product candidates and progress these compounds and product candidates through preclinical and clinical development. Although our research and development efforts to date have resulted in a pipeline of product candidates and potential product candidates directed at various cancers and other indications, we have not received regulatory approval for any of our product candidates. The scientific research that forms the basis of our efforts to develop product candidates with our proprietary technologies, including those from our ARC and GADLEN platforms, is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our platforms is both preliminary and limited. Given the novelty of our technologies, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. To our knowledge, our dual-sided fusion protein product candidates have not previously been tested in humans and may have properties that negatively impact safety or efficacy, such as greater immunogenicity when compared to existing therapeutics. Moreover, our product candidates may have unexpected biological interactions when administered *in vivo*. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates.

The successful development of our product candidates will depend on several factors, including the successful and timely completion of clinical trials and preclinical studies, successful patient enrollment in clinical trials, receipt of regulatory approvals and marketing authorizations, commercially viable manufacturing processes, and our ability to demonstrate the safety and efficacy of our product candidates.

Our ability to generate revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product, which could result in significant harm to our financial position and materially and adversely affect our share price.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel. We expect to continue to expand our capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

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.

We expect to experience continued 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 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 our anticipated 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 company with such anticipated growth, 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.

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

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 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. 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. As mentioned herein, our product candidates and technology platforms are novel and entail significant complexity.

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 ongoing or 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. Additionally, any safety concerns observed in any one of our 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.

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. The interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. For example, safety, pharmacokinetic, and pharmacodynamic data are different than, and may not be predictive of, clinical efficacy endpoints. As a result, interim, topline, or preliminary data should be viewed with caution until the final data are available.

Interim, topline, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Material differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of interim, topline, or preliminary data by us or by our competitors could impact our ability to enroll our clinical trials and influence industry expectations, which could result in volatility in the price of our common stock and affect our ability to raise additional capital.

Clinical drug development is a lengthy and expensive process with uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and, therefore, be unable to 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 effective and safe 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 then 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 of one or more clinical trials can occur at any stage of testing. 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.

Additionally, all of our trials, including our ongoing Phase 1 trials evaluating SL-172154, are open-label trials in which both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing approved therapy. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs 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 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. While we believe that the targeted nature of our dual-sided fusion proteins may carry a lower risk of overstimulating the immune system and causing a cytokine storm (a side effect associated with certain other antibody therapies), we do not have enough clinical data and experience with these molecules in humans to fully anticipate side effects. Accordingly, we may experience unexpected side effects and/or higher levels of known side effects in clinical trials, such as cytokine storms associated with certain immunotherapies or red blood cell lysis associated with some CD47 targeting therapies.

Results of our clinical trials could reveal a high and unacceptable severity and/or prevalence of these or other 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 harm our business and financial condition significantly.

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 clinical trials, our research and development efforts, business, financial condition, and results of operations could be materially and adversely affected.

Successful and timely completion of clinical trials will require that we initiate our clinical trial sites in a timely manner and enroll a sufficient number of patient candidates. Trials have been and may continue to 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 adverse events.

Our clinical trials 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 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. Moreover, enrolling patients in clinical trials for cancer therapies is challenging, as cancer patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care therapy, such as PD-1 checkpoint inhibitors, (and thus do not enroll in clinical trials) are believed to have tumor types that may have responded well to our product candidates. This may limit the number of eligible patients able to

enroll in our clinical trials and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these patients may have either compromised immune function from prior administration of chemotherapy or an enhanced immune response from the prior administration of checkpoint inhibitors. Either of these prior treatment regimens may render our therapies less effective in clinical trials. We have sought and may continue to seek to mitigate these effects in the future through modification of enrollment eligibility criteria, including patients with tumor types that are not typically responsive to anti-PD-1 antibodies, or pursuing combination regimens early in clinical development to enable access to anti-PD-1 naïve patients. Additionally, patients who have failed approved therapies will typically have more advanced cancer and a poorer long-term prognosis.

If we are unable to initiate or adequately enroll our clinical trial sites in the United States, Canada, and Europe, 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. For example, we have not yet received the requisite approval to initiate our Phase 1 clinical trials for SL-172154 in Spain and we may not receive such approval, which has impacted, and may continue to impact in the future, our ability to enroll patients and the expected timeline for such trials. 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.

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. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, or the IRA, which, among other provisions, included several measures intended to lower the cost of prescription drugs and enact related healthcare reforms. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

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. 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. 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."

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 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.

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.

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, or 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.

Risks Related to Commercialization of Our Product Candidates

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.

Our success is highly dependent on our ability to expeditiously discover, develop, and obtain marketing approval for new and innovative products on a cost-effective basis and market them successfully. With the proliferation of new therapies, including oncology drugs and immuno-therapies, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological innovation, we may be unable to compete effectively.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized by line of therapy (first, second, third, fourth, etc.), and the FDA often initially approves new therapies only for use in a particular line or lines of therapy. For example, we may initially seek approval of our product candidates as a third-line therapy for patients who have failed other approved treatments. We may subsequently seek approval as a second- and first-line therapy. There is no guarantee that our product candidates, even if initially approved,

would be subsequently approved as a second or first line therapy. Because the potentially addressable patient target population for our product candidates may be limited to patients who are ineligible for or have failed prior treatments, even if we obtain significant market share for our product candidates, we may never achieve profitability.

We may pursue the development of our product candidates in combination with other approved therapeutics. If the FDA revokes approval of any such therapeutic, or if safety, efficacy, manufacturing, or supply issues arise with any therapeutic that we use in combination with one of our product candidates in the future, we may be unable to further develop and/or market our product candidate or we may experience significant regulatory delays or supply shortages, and our business could be materially and adversely affected.

We may pursue the development of our product candidates in combination with other approved therapeutics, and we may commence clinical trials of our product candidates in combination with other approved therapeutics in the future. If we were to commence a combination trial, we will not have developed or obtained regulatory approval for, nor will we manufacture or sell, any of these approved therapeutics. In addition, the combinations will likely not have been previously tested and may, among other things, fail to demonstrate synergistic activity, fail to achieve superior outcomes relative to the use of single agents or other combination therapies, exacerbate adverse events associated with one of our product candidates when used as monotherapy, or fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

If the FDA revokes its approval of any combination therapeutic, we would not be able to continue clinical development of or market any product candidate in combination with such revoked therapeutic. If safety or efficacy issues were to arise with therapeutics that we seek to combine with, we could experience significant regulatory delays, and the FDA could require us to redesign or terminate the applicable clinical trials. In addition, we may need, for supply, data referencing, or other purposes, to collaborate or otherwise engage with the companies who market these approved therapeutics. If we are unable to do so on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate or indication, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities.

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

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity under the BPCIA. 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. See "Business—Government Regulation—Biosimilars and Reference Product Exclusivity."

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 product candidates is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls that are in compliance with current Good Manufacturing Practices, or cGMP. We do not currently own or operate any cGMP manufacturing facilities, nor do we have any in-house cGMP manufacturing capabilities. We rely on third-party contract manufacturers to produce sufficient quantities of materials required for the manufacture, transport, and storage of our compounds and product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards. If we are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially and adversely harm our business.

We currently rely on a limited number of manufacturers for BDS. The loss of one or more of our current manufacturers or their failure to supply us with BDS on a timely basis could result in our inability to develop and manufacture our product candidates, which could materially and adversely affect our business. The process for identifying additional BDS manufacturers and successfully producing BDS with those manufacturers is lengthy and expensive, and there can be no assurance that any additional manufacturers will be able to successfully produce satisfactory BDS on a timely basis or at all. If we are not able to successfully produce BDS with additional manufacturers, our existing manufacturers may need to increase manufacturing capacity to meet anticipated demand, which could involve significant challenges.

Because we rely on a limited number of third-party manufacturers to provide our BDS, there can be no assurance that our supply of BDS will not be limited or interrupted, have satisfactory quality or product characteristics, or continue to be available at acceptable prices. There can also be no assurance that our manufacturers will continue to meet regulatory requirements for cGMP manufacturing. As is common in our industry, we have experienced enrollment delays in our clinical trials as a result of

delays in receipt of BDS. We have limited control over the process or timing of the acquisition or manufacture of materials by our manufacturers, and cannot ensure that they will deliver to us the BDS we order on time, or at all.

In the normal course of business, the process of manufacturing our product candidates has been 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. Even minor deviations from normal manufacturing processes, which we have experienced, may result in reduced production yields and other supply disruptions, including delays in receipt of product candidates for our clinical trials. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, this could lead to withdrawal of our products from the market, and such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

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 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, nonclinical, and clinical programs. We rely on these parties for execution of certain preclinical studies and clinical trials, and 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 GLP, or good clinical practice, or GCP, 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.

The investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials. 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 existing or future collaborative 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 entered into, and may decide in the future to enter into, collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of certain 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 our collaboration partner adequately protects and does not misuse our intellectual property. We and our collaboration partner 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. 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 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 product candidates from our ARC and GADLEN platforms, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those product candidates.

The prosecution, enforcement, defense, and maintenance of intellectual property rights is 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 immune-

oncology space; complicated and unforgiving procedural, documentary, and fee requirements of the U.S. Patent & Trademark Office, or USPTO, 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 those from our ARC or GADLEN platforms. 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. For example, we are aware of a patent that may impact our competitive position with respect to SL-172154. The patent lists claims that generally relate to methods of using fusion proteins to treat certain types of cancers. While we believe that the claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful, in which case we may be required to obtain a license in order to commercialize our product candidate, if approved. The targets of our product candidates have also been the subject of research by many companies that have filed patent applications or have patents related to such targets and therapeutics methods related to those targets.

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.

In addition, 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 depend on intellectual property licensed from third parties and if we fail to comply with our obligations under any license, collaboration 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 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. In the United States, there have been numerous changes to the patent laws and proposed changes to the rules of the USPTO that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act, enacted in 2011, involved significant changes in patent legislation. The Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken 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 USPTO, 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 USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO 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. 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 Part I, Item 1. “Business—Government Regulation—Data Privacy and Security.” 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.

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, or Nasdaq, 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 are the subject of putative securities class action cases against the Company and certain of our officers and directors, alleging that defendants made false or misleading statements. This type of litigation, and others like 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.

As of February 1, 2023, 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.

General Risk Factors

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, 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 extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. 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.

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. If any analyst who may cover us 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 other unfavorable commentary or research.

The requirements of being a public company may strain our resources, result in more 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. 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. See the discussion of Legal Proceedings in Part I, Item 3 of this Form 10-K.

Class-action 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 increase in 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. See the discussion of Legal Proceedings in Part I, Item 3 of this Form 10-K.

We may become exposed to costly and damaging liability claims, either when testing our 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 current and future use of our 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 our 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 Securities Exchange Act of 1934, as amended, or 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, 2022, we had U.S. federal and state net operating loss, or NOL, carryforwards of $118.4 million and $0.2 million, respectively, which may be available to offset future taxable income. As of December 31, 2022, we also had gross federal tax credits of $12.5 million, which may be used to offset future tax liabilities. These NOLs and tax credit carryforwards will begin to expire in 2024. 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 2. Properties

Our corporate headquarters are located in Austin, Texas where we currently occupy approximately 8,000 square feet of office space under a lease that expires on September 30, 2026. 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

On January 31, 2022 and February 11, 2022, putative class action lawsuits were filed in the U.S. District Court for the Eastern District of New York against us and certain of the Company's officers and directors. The cases were consolidated on June 2, 2022, and the plaintiffs filed an amended complaint on July 1, 2022. The amended complaint cites the volatility in the Company's common stock and alleges that the defendants made or are responsible for misleading omissions regarding the Company's clinical trial results and Collaboration Agreement with Takeda. The parties reached a settlement in principle of the plaintiffs' claims in the amount of $1.4 million on November 2, 2022. The settlement is subject to a definitive settlement agreement, notice to stockholders and court approval. The parties filed their motion for preliminary approval of the settlement agreement with the court on December 14, 2022, and, as of February 22, 2023, that motion is pending.

We are not presently a party to any other legal proceedings 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

None.

Part II.

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

Our common stock is traded on The Nasdaq Global Select Market under the symbol "STTK". At February 1, 2023, there were approximately 31 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

The Company has never paid dividends on its Common Stock and does not anticipate that it will do so in the foreseeable future.

Use of Proceeds from Initial Public Offering of Common Stock

There has been no material change in our intended use of proceeds from our initial public offering, or IPO, as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 13, 2020.

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 audited 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 an innovative clinical-stage biotechnology company pioneering the development of dual-sided fusion proteins as an entirely new class of biologic medicine. We have created a novel approach to immune modulation by designing biologics with structural characteristics that may not be achievable by existing therapeutic modalities, including monoclonal or bispecific antibodies. Compounds derived from our proprietary Agonist Redirected Checkpoint, or ARC®, platform simultaneously inhibit checkpoint molecules and activate costimulatory molecules with a single therapeutic.

Our lead product candidate, SL-172154, is designed to simultaneously inhibit the CD47/SIRPα macrophage checkpoint interaction and activate the CD40 costimulatory receptor to induce an antitumor immune response. Coupling CD40 activation with CD47 inhibition differentiates SL-172154 from all other clinical-stage CD47/SIRPα inhibitors in development, and in our published preclinical studies, SL-172154 resulted in superior antitumor immunity as compared to certain CD47/SIRPα inhibitors. We are pursuing a broad clinical development strategy in both solid and hematologic tumors, with multiple ongoing clinical trials. SL-172154 is in an ongoing Phase 1 clinical trial for the treatment of patients with ovarian cancer. We are also evaluating SL-172154 in an ongoing Phase 1 clinical trial for the treatment of patients with certain hematologic malignancies, including acute myeloid leukemia, or AML, and higher-risk myelodysplastic syndromes, or HR-MDS. We believe our clinical development plan may provide both first-in-class and best-in-class development opportunities for SL-172154.

We believe that data shared to date in human cancer patients have demonstrated that the unique protein engineering and physical properties of the ARC platform have led to a differentiated profile in terms of safety and on-target immune activation, demonstrated by unique pharmacodynamic findings, as compared to monoclonal or bispecific antibodies.

In addition to our clinical-stage ARC product candidate, we possess a deep pipeline of potential product candidates in preclinical development. As an example, SL-9258, an ARC compound in preclinical development, is designed to inhibit the TIGIT/PVR checkpoint interaction while simultaneously activating HVEM and LTβ costimulatory receptors.

Furthermore, our expertise in dual-sided fusion proteins has led to the development of a second novel platform technology. We call this our gamma delta T cell engager, or GADLEN™, platform. The most advanced compounds from this platform are a CD20-directed GADLEN and a B7-H3-directed GADLEN.

Longer-term, we are pursuing additional disease areas, including autoimmune diseases, where our dual-sided fusion protein platforms may provide advantages over current treatment modalities.

Overview of Operations

Since our inception in 2016, we have devoted substantially all of our resources to conducting research and development activities, including undertaking nonclinical studies of our product candidates, conducting clinical trials of our most advanced product candidates, manufacturing our product candidates, developing and perfecting our intellectual property rights, organizing and staffing our company, business planning, and raising capital. We do not have any products approved for sale, and we have not generated any revenue from product sales. We have funded our operations as of the filing date of this Annual Report on Form 10-K through the net proceeds from our IPO of approximately $213.5 million, the sale of redeemable convertible preferred stock for approximately $152.9 million, the issuance of convertible notes for approximately $10.5 million and payments received pursuant to our collaboration agreements for approximately $82.7 million.

For the years ended December 31, 2022 and 2021, our net loss was $101.9 million and $45.0 million, respectively. We have not been profitable since inception, and as of December 31, 2022, we had an accumulated deficit of $219.0 million and $161.3 million in cash and cash equivalents and 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 to advance the nonclinical and clinical development of our clinical-stage product candidate, SL-172154;
- initiate nonclinical studies and clinical trials for additional product candidates that we may identify in the future;
- manufacture sufficient quantities of bulk drug substance and drug product to support our ongoing and planned nonclinical studies and clinical trials;
- continue our process development efforts for our current and future product candidates;
- maintain our operational, financial, and management systems;
- retain key personnel and infrastructure to support our clinical development, research and manufacturing 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.

COVID-19 Pandemic

As a result of the COVID-19 pandemic, we have experienced, and expect to continue to experience, delays in our clinical trials. Our manufacturing operations have also been impacted, including delays with certain third-party manufacturers and difficulties in obtaining raw materials needed to manufacture material for our clinical trials. Additionally, we have experienced, and expect to continue to experience, delays in enrolling patients, missed treatments for enrolled patients, and performance delays from certain third-party vendors supporting our clinical trials, although the significance of any future delays is difficult to predict.

Certain of our research and development activities, including the conduct of nonclinical studies, have been delayed and may be further delayed due to the impact of the COVID-19 pandemic. The COVID-19 pandemic or local outbreaks associated with the COVID-19 pandemic could result in difficulty manufacturing our product candidates, securing clinical trial site locations, CROs; and/or trial monitors and other critical vendors and consultants supporting our clinical trials. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact our ability to enroll patients or to complete all scheduled physician visits for currently enrolled patients. These situations, or others associated with COVID-19

pandemic, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material and adverse effect on our business and its financial condition. At the current time, we are unable to quantify the potential effects of the COVID-19 pandemic on our future operations.

Global Economic Considerations

In addition, the global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine and other political tensions, and lingering effects of the COVID-19 pandemic. Such challenges have caused, and may continue to cause, recession fears, rising 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.

Collaboration Agreement - Takeda

On August 8, 2017, we entered into the Collaboration Agreement with Takeda. The Collaboration Agreement was mutually terminated pursuant to the Termination Agreement. Under the terms of the Termination Agreement, we are not required to satisfy any remaining performance obligations, we will not make any payments to or receive any future milestone or royalty payments from Takeda, and all options to license and rights of first negotiation held by Takeda under the Collaboration Agreement were terminated.

Components of our Results of Operation

Collaboration Revenue

We have no products approved for commercial sale, and we have not generated any revenue from commercial product sales. Our total revenue to date has been generated from our Collaboration Agreement with Takeda, and a research agreement with another third-party pharmaceutical company that was initiated and completed in 2022.

Additionally, we have entered into the Clinical Trial Collaboration Agreement with ImmunoGen, under which we expect to recognize up to $2.0 million of revenue, beginning in 2023 and continuing into or through 2024.

We continue to explore other potential collaborations and expect that collaboration revenue we may generate, if any, will fluctuate from period to period.

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 nonclinical studies and clinical trials;
- 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;
- 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, 2022	2021
SL-172154	$ 38,609	$ 15,708
Other pipeline compounds	17,373	24,835
Internal costs, including personnel related benefits, facilities, and depreciation	26,917	16,020
	$ 82,899	$ 56,563

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, including increased demand for clinical trial material. We expect to incur significant research and development expenses throughout 2023. While it is difficult for us to predict with certainty, we expect increasing year-over-year operating expense over the next several years in the event that we conduct additional nonclinical studies and clinical trials (beyond our currently planned clinical trials), including later-stage clinical trials, for our current and future product candidates, pursue regulatory approval of our product candidates, or advance our preclinical pipeline.

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;
- early clinical data for our product candidates;
- investment in our clinical programs;
- 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.

We expect that our general and administrative expense may increase in the future to support our ongoing research and development activities and as a result of the costs of operating as a public company. These increases may include increased costs related to the retention of personnel and fees paid to outside consultants, lawyers, and accountants, among other expenses. Additionally, we anticipate that we will continue to incur significant costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the Securities and Exchange Commission, or SEC, insurance, and investor relations costs. If any of our current or future product candidates advances to later-stage clinical development or obtains regulatory approval, we expect that we would incur significantly 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, respectively.

Other Income

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

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net operating losses, or 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 NOLs and tax credit carryforwards will begin to expire in 2024. 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, 2022 and 2021

The following table sets forth our results of operations for the years ended December 31, 2022 and 2021.

(in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021	Change Dollar	Change Percentage
Collaboration revenue	$ 652	$ 30,017	$ (29,365)	(97.8)%
Operating expenses:				
Research and development	82,899	56,563	26,336	46.6 %
General and administrative	21,082	18,723	2,359	12.6 %
Loss from operations	(103,329)	(45,269)	(58,060)	128.3 %
Other income	1,384	295	1,089	369.2 %
Net loss	$ (101,945)	$ (44,974)	$ (56,971)	126.7 %

Collaboration Revenue

Collaboration revenue decreased by $29.4 million, or (97.8)%, to $0.7 million for the year ended December 31, 2022 from $30.0 million for the year ended December 31, 2021. This decrease is primarily attributable to the cessation of work with Takeda under the Collaboration Agreement, which was mutually terminated in the fourth quarter of 2021 and all remaining revenue was recognized at that time. In the second quarter of 2022, we executed a collaboration agreement with another third party. We completed the work in the fourth quarter of 2022 and have recognized all of the revenue associated with that agreement.

Research and Development Expense

Research and development expenses increased by $26.3 million, or 46.6%, to $82.9 million for the year ended December 31, 2022 from $56.6 million for the year ended December 31, 2021. The increase was primarily due to an increase of $8.4 million in manufacturing costs related to the manufacture of clinical trial material for our ongoing clinical trials, an increase of $7.5 million as a result of an increase in headcount to expand our in-house research, manufacturing and clinical development capabilities, an increase of $4.3 million for facility and equipment expenses related to our increased lab space and related research activities, an increase of $3.2 million in clinical trial costs and an increase of $3.2 million in other operating expenses primarily related to fixed asset depreciation and impairment losses, offset by a decrease of $1.2 million in pharmacology costs.

General and Administrative Expense

General and administrative expenses increased by $2.4 million, or 12.6%, to $21.1 million for the year ended December 31, 2022 from $18.7 million for the year ended December 31, 2021. The increase was primarily driven by a litigation settlement of $1.4 million and an increase of $0.6 million of costs associated with being a public company.

Liquidity and Capital Resources

Since our inception, our primary sources of liquidity have been generated by sales of our preferred stock and common stock, including our IPO, and collaboration agreements. As of December 31, 2022, we had an accumulated deficit of $219.0 million and $161.3 million of cash and cash equivalents and investments.

In July 2022, we entered into a sales agreement, or the Sales Agreement, with SVB Securities LLC, or 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 in the ATM Facility. The Sales Agent is generally entitled to compensation at a commission equal to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement. As of December 31, 2022, there were no sales pursuant to the ATM Facility.

Capital Resources and Funding Requirements

Our primary uses of cash and cash equivalents and 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 and cash equivalents and investments as of December 31, 2022 are sufficient to fund projected operations into the second half of 2024.

Cash Flows

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

	Year ended December 31,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (94,498)	$ (57,116)
Net cash provided by (used in) investing activities	49,438	(10,443)
Net cash provided by financing activities	171	1,929
Net decrease in cash and cash equivalents	$ (44,889)	$ (65,630)

Net Cash Used in Operating Activities

During the year ended December 31, 2022, net cash used in operating activities was $94.5 million and primarily reflected by our net loss of $101.9 million and a $4.5 million net change in our operating assets and liabilities, offset by noncash charges of $6.5 million in stock-based compensation, $4.7 million in depreciation expense, amortization of investments and non-cash operating lease expense and $0.7 million in losses on sale of assets. 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, 2021, net cash used in operating activities was $57.1 million and primarily reflected by our net loss of $45.0 million and a $22.0 million net change in our operating assets and liabilities, offset by noncash charges of $5.5 million in stock-based compensation and $4.4 million in depreciation expense and amortization of investments.

Net Cash Provided by (Used in) Investing Activities

During the year ended December 31, 2022, net cash provided by investing activities was $49.4 million of which $60.9 million represents the net change in investments and $11.5 million represents purchases of property and equipment, net of sales, primarily attributable to our continued efforts to bring certain process development, manufacturing and laboratory capabilities in-house.

During the year ended December 31, 2021, net cash used in investing activities was $10.4 million of which $7.9 million was used to purchase property and equipment, primarily attributable to our continued efforts to bring certain process development, manufacturing and laboratory capabilities in-house and $2.5 million represents the net change in investments.

Net Cash Provided by Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $0.2 million and was from the exercise of stock options and purchases pursuant to our employee stock purchase plan.

During the year ended December 31, 2021, net cash provided by financing activities was $1.9 million and was from 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, or GAAP. 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 collaboration agreements with other companies. 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 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, 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 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, or RSUs, 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 and Monte Carlo option-pricing models require 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 8 to our audited 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 and Monte Carlo option pricing models to determine the estimated fair value of our stock options granted during the year ended December 31, 2022.

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

We are an emerging growth company as defined in the JOBS Act. Under the JOBS Act, an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We have evaluated the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (1) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of our IPO, (ii) in which we have total annual gross revenues of at least $1.07 billion or (iii) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company" as defined under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company if either (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. If we are a smaller reporting company at the time we cease to be an emerging growth 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 audited 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 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Audited Financial Statements

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, 2022 and 2021, the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the years then ended, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases as of January 1, 2022 due to the adoption of Accounting Standards Update (ASU) 2016-02, "Leases" (Topic 842).

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.

/s/ KPMG LLP

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

Austin, Texas
February 23, 2023

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 47,379	$ 92,268
Investments	113,901	176,536
Prepaid expenses and other current assets	23,304	19,462
Total current assets	184,584	288,266
Property and equipment, net	17,671	9,938
Other assets	3,069	381
Total assets	$ 205,324	$ 298,585
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,170	$ 10,012
Accrued expenses and other current liabilities	17,795	14,574
Total current liabilities	24,965	24,586
Non-current operating lease liabilities	4,202	—
Deferred rent	—	2,213
Total liabilities	29,167	26,799
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value: 300,000,000 shares authorized, 42,390,586 shares issued and outstanding at December 31, 2022 and 42,338,898 shares issued and outstanding at December 31, 2021	5	5
Additional paid-in capital	396,041	389,408
Accumulated other comprehensive loss	(877)	(560)
Accumulated deficit	(219,012)	(117,067)
Total stockholders' equity	176,157	271,786
Total liabilities and stockholders' equity	$ 205,324	$ 298,585

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,	
	2022	2021
Collaboration revenue	$ 652	$ 30,017
Operating expenses:		
Research and development	82,899	56,563
General and administrative	21,082	18,723
Expense from operations	103,981	75,286
Loss from operations	(103,329)	(45,269)
Other income (expense):		
Interest income	1,592	625
Other	(208)	(330)
Total other income	1,384	295
Net loss	$ (101,945)	$ (44,974)
Unrealized loss on investments	(317)	(497)
Comprehensive loss	$ (102,262)	$ (45,471)
Net loss per share - basic and diluted	$ (2.41)	$ (1.07)
Weighted-average shares outstanding - basic and diluted	42,378,895	42,032,384

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 Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	41,767,431	$ 5	$ 382,012	$ (63)	$ (72,093)	$ 309,861
Exercise of stock options and purchases pursuant to employee stock purchase plan	559,715	—	1,929	—	—	1,929
Vesting of common stock previously subject to vesting requirements	11,752	—	—	—	—	—
Stock-based compensation expense	—	—	5,467	—	—	5,467
Unrealized loss on investments	—	—	—	(497)	—	(497)
Net loss	—	—	—	—	(44,974)	(44,974)
Balance at December 31, 2021	42,338,898	$ 5	$ 389,408	$ (560)	$ (117,067)	$ 271,786
Exercise of stock options and purchases pursuant to employee stock purchase plan	51,688	—	171	—	—	171
Stock-based compensation expense	—	—	6,462	—	—	6,462
Unrealized loss on investments	—	—	—	(317)	—	(317)
Net loss	—	—	—	—	(101,945)	(101,945)
Balance at December 31, 2022	42,390,586	$ 5	$ 396,041	$ (877)	$ (219,012)	$ 176,157

See accompanying notes to financial statements

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

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (101,945)	$ (44,974)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	6,462	5,467
Depreciation	3,073	1,380
Net amortization of premium on investments	1,370	3,035
Loss on sale of assets	704	—
Non-cash operating lease expense	302	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,842)	(9,272)
Other assets	(53)	(32)
Accounts payable	(2,842)	7,866
Accrued expenses and other current liabilities	2,975	6,924
Non-current operating lease liabilities	(702)	—
Deferred revenue	—	(29,034)
Deferred rent	—	1,524
Net cash used in operating activities	(94,498)	(57,116)
Cash flows from investing activities:		
Purchases of property and equipment	(11,614)	(7,926)
Sale of property and equipment	104	—
Sale and maturities of investments	193,325	201,575
Purchases of investments	(132,377)	(204,092)
Net cash provided by (used in) investing activities	49,438	(10,443)
Cash flows from financing activities:		
Proceeds from the exercises of stock options and purchases pursuant to employee stock purchase plan	171	1,929
Net cash provided by financing activities	171	1,929
Net decrease in cash and cash equivalents	(44,889)	(65,630)
Cash and cash equivalents, beginning of period	92,268	157,898
Cash and cash equivalents, end of period	$ 47,379	$ 92,268
Supplemental disclosures of non-cash financial activities:		
Operating lease liabilities recognized for operating right-of-use assets	$ 5,447	$ —
Operating right-of-use assets exchanged for operating lease liabilities	$ 2,945	$ —
Unpaid amounts related to purchase of property and equipment	$ —	$ 392

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 clinical-stage biopharmaceutical company developing dual-sided fusion proteins, including its Agonist Redirected Checkpoint ("ARC®") and gamma delta T cell engager ("GADLEN™") platforms, as novel classes of biologic medicines capable of multifunctional activity with potential applications in oncology and inflammatory diseases. Using its proprietary technology, the Company is building a pipeline of therapeutics, initially focused on the treatment of solid tumors and hematologic malignancies. The Company has one clinical-stage product candidate, SL-172154, and has several compounds in preclinical development.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $219.0 million as of December 31, 2022. 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 investments of $161.3 million as of December 31, 2022 are sufficient to fund projected operations of the Company for at least the next twelve months.

COVID-19 Pandemic

The COVID-19 pandemic has had, and may continue to have, a broad adverse impact on the economies and financial markets of many countries, including the geographical areas in which the Company operates and conducts its business and in which the Company's partners operate and conduct their business. The Company and its third-party vendors and consultants have experienced disruptions to their businesses as a result of the COVID-19 pandemic. Specifically, the outbreak has caused disruptions in the Company's ability to manufacture clinical trial materials, including the acquisition of raw materials needed for such manufacturing, enrollment and treatment of patients in clinical trials, and slowdowns and shutdowns of the laboratories and other service providers that are being relied upon in the development of the Company's product candidates.

The extent to which the COVID-19 pandemic or any other health epidemic may impact the Company's results will depend on future developments, which are uncertain and cannot be predicted. Accordingly, the COVID-19 pandemic could have a material and adverse effect on the Company's business, results of operations and financial condition.

Global Economic Considerations

In addition, the global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine and other political tensions, and lingering effects of the COVID-19 pandemic. Such challenges have caused, and may continue to cause, recession fears, rising 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.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying audited 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 stated below 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 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 investments. The Company maintains its cash and cash equivalents at two accredited financial institutions 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 invests in only highly rated debt securities that management believes protects the Company from risk of default and impairment of value.

Substantially all of the Company's revenue through 2021 was derived from its 2017 collaboration agreement (the "Collaboration Agreement") with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"), which was mutually terminated in 2021.

The Company is highly dependent on a limited number of contract manufacturing organizations ("CMOs") to supply drug products for its research and development activities of its programs, including clinical trials and non-clinical studies. 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 $3.5 million held in operating accounts and $43.9 million held in money market funds as of December 31, 2022 and $14.6 million held in operating accounts and $77.7 million held in money market funds as of December 31, 2021.

Investments

The Company's 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. Unrealized gains or losses not related to credit impairments are recorded in accumulated other comprehensive income (loss), 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. As of December 31, 2022, there were no impairments related to credit losses of investments.

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 year ended December 31, 2022, the Company recorded $0.7 million 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. There were no impairments of long-lived assets for the year ended December 31, 2021.

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. The Company has elected to not apply the recognition requirement of Accounting Standards Codification (“ASC”) 842, *Leases* (“ASC 842”) of the Financial Accounting Standards Board (“FASB”) to leases with a term of 12 months or less for all classes of assets.

Commitments and Contingencies

The Company follows ASC 450-20, *Contingencies* of the FASB to report accounting for contingencies. Certain conditions may exist as of the date the condensed 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 condensed 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, 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).

To date, the Company has not granted a development and commercialization license nor recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

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* and will recognize the payments received from these agreements as revenue when the related costs are incurred.

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 CMOs. The Company accrues for expenses resulting from obligations under agreements with CROs, CMOs 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, CMOs 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, CMO 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.

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. 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, 2022 and 2021, as they would be anti-dilutive:

	As of December 31,	
	2022	2021
Stock options	4,209,255	2,448,676
Unvested restricted stock	309,477	—
	4,518,732	2,448,676

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 the net loss and unrealized gains and losses on investments.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASC 842, which requires a lessee to record a ROU asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The FASB deferred the effective date of this Accounting Standards Update until the annual periods beginning after December 15, 2021. The Company adopted this pronouncement effective January 1, 2022. See Note 6 for the impact on the financial statements. No prior period amounts were adjusted and such prior period amounts continue to be reported in accordance with previous lease guidance, ASC 840, *Leases* ("ASC 840"). The Company elected to use all of the available practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed the Company to carry forward the historical lease classification of those leases in place as of January 1, 2022.

The following table summarizes the impact of the adoption of ASC 842 on the accompanying balance sheet as of January 1, 2022 (in thousands):

	December 31, 2021	Effect of the Adoption of ASC 842	January 1, 2022
Other assets (1)	$ 381	$ 2,945	$ 3,326
Lease liabilities:			
Accrued expenses and other current liabilities (2)	$ 14,574	$ 255	$ 14,829
Non-current operating lease liabilities	$ —	$ 4,903	$ 4,903
Deferred rent (3)	$ 2,213	$ (2,213)	$ —

1 Operating lease right-of-use assets are classified within other assets.

2 Current operating lease liabilities are classified within accrued expenses and other current liabilities. Current deferred rent was classified within accrued expenses as of December 31, 2021.

3 Non-current deferred rent was classified within deferred rent as of December 31, 2021.

3. Investments

The following table represents the Company's available for sale investments by major security type (amounts in thousands):

	December 31, 2022		
	Amortized Cost	Gross Unrealized Loss	Total Fair Value
Investments:			
U.S. government securities	$ 114,778	$ (877)	$ 113,901
Total investments	$ 114,778	$ (877)	$ 113,901

	December 31, 2021		
	Amortized Cost	Gross Unrealized Loss	Total Fair Value
Investments:			
U.S. government securities	$ 177,096	$ (560)	$ 176,536
Total investments	$ 177,096	$ (560)	$ 176,536

The Company's investment instruments and cash and cash equivalents are classified using Level 1 inputs within the fair value hierarchy and are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Debt securities have an average maturity of 0.37 years as of December 31, 2022.

4. Property and Equipment

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

	December 31,	
	2022	2021
Lab equipment	$ 15,547	$ 5,823
Leasehold improvements	7,086	3,709
Furniture and fixtures	452	459
Office equipment	191	206
Construction in progress	104	2,521
	23,380	12,718
Accumulated depreciation and amortization	(5,709)	(2,780)
Property and equipment, net	$ 17,671	$ 9,938

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $3.1 million and $1.4 million, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (amounts in thousands):

	December 31,	
	2022	2021
Research and development contract costs	$ 11,256	$ 10,253
Compensation and related benefits	3,967	3,320
Litigation settlement	1,400	—
Other current liabilities	1,172	1,001
Total accrued expenses and other current liabilities	$ 17,795	$ 14,574

6. Commitments and Contingencies

Operating Leases

The Company leases certain office space, laboratory facilities, and equipment. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include renewal options at the election of the Company to renew or extend the lease. These optional periods have not been considered in the determination of the ROU assets or lease liabilities associated with these leases as the Company did not consider it reasonably certain it would exercise the options. The Company performed evaluations of its contracts and determined it has operating leases.

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

Balance Sheet Classification	December 31, 2022
Other assets	$ 2,635
Accrued expenses and other current liabilities	$ 701
Non-current operating lease liabilities	4,202
Total liabilities	$ 4,903

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

	December 31, 2022
Lease term (years)	5.5
Discount rate	8.64 %

The Company incurred rent expense for its operating leases of $0.8 million and $0.7 million during the years ended December 31, 2022 and 2021, respectively, 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 year ended December 31, 2022 was $1.0 million and was included in net cash used in operating activities in the statement of cash flows.

The maturities of the Company's operating lease liabilities as of December 31, 2022 were as follows (in thousands):

2023	$	1,089
2024		1,120
2025		1,152
2026		1,093
2027		848
Thereafter		873
Total lease payments	$	6,175
Less:		
Imputed interest		(1,272)
Total	$	4,903

As of December 31, 2021, future annual minimum lease payments, as defined under the previous lease accounting guidance of ASC 840, due under non-cancelable operating leases at December 31 of each year are as follows (in thousands):

2022	$	986
2023		1,089
2024		1,120
2025		1,152
2026		1,093
Thereafter		1,722
Total minimum lease payments	$	7,162

Nighthawk Biosciences, Inc. License Agreement

In connection with a license agreement with Nighthawk Biosciences, Inc. ("Nighthawk"), the Company is required to make payments of up to $20.6 million in aggregate for the achievement of specified development, regulatory and commercial sales milestones for certain licensed products. The Company is required to pay Nighthawk a percentage of upfront fees or other non-royalty payments not tied to milestone events that it receives in connection with certain sublicenses of the licensed patents. The Company is also required to pay Nighthawk a royalty on all of its worldwide net sales, those of its affiliates, and sublicenses of certain licensed patents in the low single digits. The Company has not recorded a liability for the aforementioned payments given the achievement of specified development, regulatory and commercial sales milestones for certain licensed products is not probable as of the balance sheet date.

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. On January 31, 2022 and February 11, 2022, putative class action lawsuits were filed in the U.S. District Court for the Eastern District of New York against us and certain of the Company's officers and directors. The cases were consolidated on June 2, 2022, and the plaintiffs filed an amended complaint on July 1, 2022. The amended complaint cites the volatility in the Company's common stock and alleges that the defendants made or are responsible for misleading omissions regarding the Company's clinical trial results and the Collaboration Agreement with Takeda. The parties reached a settlement in principle of the plaintiffs' claims in the amount of $1.4 million on November 2, 2022. The settlement is subject to a definitive settlement agreement, notice to stockholders and court approval. The parties filed their motion for preliminary approval of the settlement agreement with the court on December 14, 2022, and, as of February 22, 2023, that motion is pending. The Company has accrued the settlement amount in accrued expenses and other current liabilities as of December 31, 2022.

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 CMOs 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 CMO

and CRO agreements may be different depending on the timing of receipt of goods or services or 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.

7. Collaboration Agreements

The Company recognizes revenue for the allocated up-front payments 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. In the second quarter of 2022, the Company executed a collaboration agreement with a third party and completed the work in the fourth quarter of 2022. The company recognized $0.7 million, which represents all of the revenue associated with this agreement, in the year ended December 31, 2022.

Collaboration Agreement - Takeda

In August 2017, the Company entered into a Collaboration Agreement with Takeda related to the development of certain ARC molecules, as amended in April 2018, October 2018 and March 2020. The Collaboration Agreement was mutually terminated pursuant to a termination agreement dated November 8, 2021 (the "Termination Agreement"). Under the terms of the Termination Agreement, the Company is not required to satisfy any remaining performance obligations, the Company will not make any payments to or receive any future milestone or royalty payments from Takeda, and all options to license and rights of first negotiation held by Takeda under the Collaboration Agreement were terminated.

8. Stock-Based Compensation

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 common shares on December 31st of the preceding calendar year. The Board of Directors (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. On January 1, 2023, the share reserve automatically increased by 1,695,623 shares. As of December 31, 2022, there were 3,497,307 shares available for future grants. 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. In 2022, the Company granted 178,150 awards that vest based on the Company achieving a closing share price of equal to or greater than $18.00 for 30 consecutive trading days on or before the fourth anniversary of the grant date, and 226,543 awards that vest over two years.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan ("2020 ESPP") became effective in connection with the Company's initial public offering ("IPO"). A total of 395,795 shares of common stock were reserved for issuance under the 2020 ESPP. 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. 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. On January 1, 2023, the share reserve increased by 423,905 shares. During the years ended December 31, 2022 and 2021, the Company issued 13,088 and 2,106 shares of common stock for aggregate cash proceeds of $0.1 million and $0.1 million, respectively.

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

	Year Ended December 31,	
	2022	2021
Research and development	$ 3,574	$ 2,200
General and administrative	2,888	3,267
Total stock-based compensation	$ 6,462	$ 5,467

The following table summarizes option activity under the 2020 Plan:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Balance at December 31, 2021	2,448,676	$ 10.96	8.08
Granted	1,938,675	5.68	
Exercised	(38,600)	3.23	
Forfeited	(139,496)	16.88	
Balance at December 31, 2022	4,209,255	$ 8.29	8.07
Vested and expected to vest	4,153,436	$ 8.29	8.06
Exercisable at the end of the period	1,717,933	$ 8.24	6.87

Options granted during the years ended December 31, 2022 and 2021 had weighted-average grant-date fair values of $4.03 and $16.38 per share, respectively. As of December 31, 2022, the unrecognized compensation cost for options issued was $12.9 million and will be recognized over an estimated weighted-average amortization period of 2.29 years. The total intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was $0.1 million and $11.8 million, respectively. The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2022 was $0.2 million.

Restricted Stock Units

The following table summarizes employee RSU activity for the year ended December 31, 2022:

	Awards	Weighted Average Grant Date Fair Value
Unvested RSUs as of December 31, 2021	—	$ —
Granted	331,653	7.24
Vested	—	—
Forfeited	(22,176)	7.43
Balance at December 31, 2022	309,477	$ 7.22

The Company recognized $0.6 million of stock-based compensation related to RSUs as of December 31, 2022. As of December 31, 2022, the unrecognized compensation cost for RSUs issued was $1.7 million and will be recognized over an estimated weighted-average amortization period of 3.06 years. The fair values of RSUs are 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 Company uses the Monte Carlo pricing model to estimate the fair value of options that have market-based conditions. The inputs to both pricing models 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 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,	
	2022	2021
2020 Plan		
Expected term - years	6.08	6.08
Expected volatility	82.4%	81.4%
Risk-free interest rate	2.4%	1.1%
Expected dividends	—	—

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

	Year Ended December 31,
	2022
2020 Plan	
Expected term - years	4.00
Expected volatility	80.0%
Risk-free interest rate	1.4%
Expected dividends	—

There were no options granted that have market-based conditions during the year ended December 31, 2021.

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,	
	2022	2021
2020 ESPP		
Expected term - years	0.50	0.50
Expected volatility	82.9%	81.3%
Risk-free interest rate	2.5%	0.9%
Expected dividends	—	—

9. Income Taxes

The Company recorded no federal provision for income taxes as of December 31, 2022 and 2021 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, 2022 and 2021 (amounts in thousands):

	Year Ended December 31,	
	2022	2021
Income tax benefit computed at federal statutory tax rate	$ (21,409)	$ (9,445)
Change in valuation allowance	24,713	13,045
General business credits	(4,883)	(3,108)
Stock compensation	602	(1,923)
Section 162(m) limitation	—	809
Change in uncertain tax position	977	622
Income tax benefit	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 are as follows (amounts in thousands):

	December 31,	
	2022	2021
Deferred tax asset:		
Net operating loss carryforwards	$ 24,867	$ 20,460
Accrued expenses and other	3,578	3,520
Stock compensation	1,533	779
Credit carryforwards	10,101	6,194
Capital loss carryforwards	583	484
Capitalized R&D expense	15,017	—
Lease liabilities	1,030	—
Gross deferred tax asset	56,709	31,437
Less valuation allowance	(55,044)	(30,331)
Net deferred tax asset	1,665	1,106
Deferred tax liability:		
Depreciation and amortization	(676)	(578)
Prepaid expenses	(436)	(528)
Lease assets	(553)	—
Total deferred tax liability	(1,665)	(1,106)
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

$24.7 million and $13.0 million during the years ended December 31, 2022 and 2021, respectively, primarily due to continuing loss from operations, general business credit carryforwards, and accrued expenses.

As of December 31, 2022 and 2021, the Company had gross U.S. net operating loss ("NOL") carryforwards of $118.4 million and $97.4 million, respectively. Additionally, as of December 31, 2022 and 2021, the Company had capital loss carryforwards of $2.8 million and $2.3 million, respectively. As of December 31, 2022 and 2021, the Company had gross state NOL carryforwards of $0.2 million and $0.2 million, respectively. As of December 31, 2022 and 2021, the Company had gross U.S. tax credit carryforwards of $12.5 million and $7.6 million, respectively. The NOL, capital loss, and tax credit carryforwards will begin to expire in 2024, if not utilized. 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. After the 2019 financial statements were filed, the Company completed a Section 382 study from formation through October 14, 2020. Although an ownership change occurred during 2020, no deferred tax assets were impacted by the limitation.

A reconciliation of our liability for unrecognized tax benefits is as follows:

	Year Ended December 31,	
	2022	2021
Balance, beginning of the year	$ 1,404	$ 783
Increase for tax positions related to the current year	733	449
Increase for tax positions related to prior years	243	172
Balance, end of year	$ 2,380	$ 1,404

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, 2022, 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 2019, 2020, and 2021 tax years. There are currently no federal or state income tax audits in progress.

10. Subsequent Events

None.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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, 2022, 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 Securities Exchange Act of 1934, as amended, or 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) 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, 2022, 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. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm. For as long as we remain an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during fourth quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

Part III.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2023 Annual Meeting of Stockholders 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 heading "Directors, Executive Officers, and Corporate Governance."

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 any amendments to, or waivers from, the code of business conduct and ethics 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 Proxy Statement with respect to our 2023 Annual Meeting of Stockholders 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 "Executive Compensation" and "Directors, Executive Officers and Corporate Governance."

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2023 Annual Meeting of Stockholders 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 "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation-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 Proxy Statement with respect to our 2023 Annual Meeting of Stockholders 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 "Directors, Executive Officers and 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 Proxy Statement with respect to our 2023 Annual Meeting of Stockholders 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 heading "Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm."

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 Consolidated Financial Statements at Part II, Item 8 "Financial Statements – Audited Financial Statements."

(b) Financial Statement Schedules.

No financial statement schedules are provided because the information called for is not required or is shown 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. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918)).
4.2	Second Amended and Restated Investors' Rights Agreement, dated as of June 12, 2020, by and among Shattuck Labs, Inc. and certain of its stockholders (incorporated by reference from Exhibit 4.2 of the Company's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918)).
4.3	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).
10.1+	Form of Indemnification Agreement for directors and executive officers (incorporated by reference from Exhibit 10.1 of the Company's Amendment No. 1 to Registration Statement on Form S-1 filed on October 5, 2020 (Commission File No. 333-248918)).
10.4+	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)).
10.5+	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)).
10.6+	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 Shattuck's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593))
10.7+	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)).
10.8+	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 Shattuck's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593))
10.9+	Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Erin Ator Thomson (incorporated by reference from Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.10+	Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Erin Ator Thomson (incorporated by reference from Exhibit 10.10 of Shattuck's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593))

10.11+	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)).
10.12+	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 Shattuck's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593))
10.13+	Employment Agreement, dated December 9, 2019, by and between Shattuck Labs, Inc. and Casi DeYoung (incorporated by reference from Exhibit 10.13 of Shattuck's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593))
10.14+	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 Shattuck's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593))
10.15+	2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.9 of the Company's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918)).
10.16+	2020 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.10 of the Company's Amendment No. 2 to Registration Statement on Form S-1 filed on October 8, 2020 (Commission File No. 333-248918)).
10.17+	Non-Employee Director Compensation Policy (incorporated by reference from Exhibit 10.11 of the Company's Amendment No. 1 to Registration Statement on Form S-1 filed on October 5, 2020 (Commission File No. 333-248918)).
10.19†	Exclusive License Agreement, dated June 3, 2016, by and between Shattuck Labs, Inc. and Heat Biologics, Inc., as amended (incorporated by reference from Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.20	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)).
10.21	Lease Agreement, dated January 8, 2021, between Shattuck Labs, Inc. and International Bank of Commerce, Laredo, Texas.
10.22†	Master Services Agreement, dated March 31, 2017, between Shattuck Labs, Inc. and KBI Biopharma, Inc. (incorporated by reference from Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)).
10.23†	Takeda Termination Agreement (incorporated by reference from Exhibit 10.1 of Shattuck's Quarterly Report on Form 10-Q filed on November 9, 2022 (Commission File No. 001-39593))
10.24	Sales Agreement, dated July 29, 2022, between Shattuck Labs, Inc. and SVB Securities LLC (incorporated by reference from Exhibit 10.1 of Shattuck's Current Report on Form 8-K filed on July 29, 2022 (Commission File No. 001-2953))
10.25†	Clinical Trial Collaboration and Supply Agreement, dated February 4, 2022, by and between Shattuck Labs, Inc. and ImmunoGen, Inc.
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.
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, 2022, 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 23rd day of February 2023.

Shattuck Labs, Inc.

Date: February 23, 2023

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

Date: February 23, 2023

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed 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*)	February 23, 2023
/s/ Andrew R. Neill Andrew R. Neill	Chief Financial Officer (*principal financial and accounting officer*)	February 23, 2023
/s/ Dr. George Golumbeski Dr. George Golumbeski	Chairman of the Board	February 23, 2023
/s/ Helen M. Boudreau Helen M. Boudreau	Director	February 23, 2023
/s/ Dr. Neil Gibson Dr. Neil Gibson	Director	February 23, 2023
/s/ Dr. Carrie Brownstein Dr. Carrie Brownstein	Director	February 23, 2023
/s/ Michael Lee Michael Lee	Director	February 23, 2023
/s/ Tyler Brous Tyler Brous	Director	February 23, 2023

Exhibit 10.25

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this "**Agreement**"), made as of February 4, 2022 (the "**Effective Date**"), is by and between **Shattuck Labs, Inc.**, a Delaware corporation (**"Shattuck"**), with a place of business at 500 W. 5th Street, Suite 1200, Austin, Texas 78701 ("**Shattuck**") and **ImmunoGen, Inc.**, having a place of business at 830 Winter Street, Waltham, MA 02451-1477, USA ("**ImmunoGen**"). Shattuck and ImmunoGen are each referred to herein individually as "**Party**" and collectively "**Parties**".

RECITALS

WHEREAS, ImmunoGen is developing the ImmunoGen Compound (as defined below) for the treatment of ovarian cancer.

WHEREAS, Shattuck is developing the Shattuck Compound (as defined below) for the treatment of ovarian cancer.

WHEREAS, Shattuck is sponsoring a clinical trial exploring administration of Shattuck's proprietary molecule SL-172154 (SIRPα-Fc-CD40L) in ovarian cancer patients in combination with other therapeutic agents (the "**SL03-OHD-105 Trial**"), and the ImmunoGen Compound and the Shattuck Compound would be investigated in combination in one arm of such clinical trial.

WHEREAS, Shattuck and ImmunoGen, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Shattuck Compound and the ImmunoGen Compound for the Study (as defined below).

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1 Definitions.

For all purposes of this Agreement, the capitalized terms defined in this Section 1 and throughout this Agreement shall have the meanings herein specified.

1.1 "**Affiliate**" means, with respect to any Person, any other Person that, directly or indirectly through one or more Affiliates, controls or is controlled by or is under common control with such Person. For purposes of this definition, "control" means (a) ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, (b) status as a general partner in the case of any partnership, or (c) any other arrangement whereby a Person controls or has the right to control the board of directors or equivalent governing body or management of another Person. A Person shall be deemed an Affiliate only so long as it satisfies the foregoing definition.

1.2 "**Agreement**" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

1.3 "**Alliance Manager**" has the meaning set forth in Section 3.1.

1.4 "**Anti-Bribery and Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the U.K. Bribery Act 2010, and any other applicable anti-bribery and anti-corruption laws in any applicable country.

1.5 "Applicable Law" means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration ("FDA"), national regulatory authorities, the European Medicines Agency ("EMA") and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a "**Regulatory Authority**" and collectively, "**Regulatory Authorities**"), and including cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU Data Protection Directive and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") and any United States or other country's or jurisdiction's successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

1.6 "**Business Day**" means any day other than a Saturday, Sunday or other day on which banking institutions in Boston, Massachusetts or New York, New York are required to be closed or are actually closed with legal authorization.

1.7 "**cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compound.

1.8 "**Clinical Data**" means all data (including raw data) and results generated in the course of performance of the Study; provided, however, Clinical Data shall not include medical records and source documents of subjects participating in the Study.

1.9 "**Clinical Quality Agreement**" has the meaning set forth in Section 8.2.

1.10 "**Compounds**" means the ImmunoGen Compound and the Shattuck Compound. A "**Compound**" means either the ImmunoGen Compound or the Shattuck Compound, as applicable.

1.11 "**Combination**" means the use or method of using the ImmunoGen Compound and the Shattuck Compound in concomitant or sequential administration.

1.12 "**Confidential Information**" means with respect to a Party, all information of any kind whatsoever (including, without limitation, material, compilations, data, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies and techniques), and all tangible and intangible embodiments thereof of any kind whatsoever (including, without limitation, any apparatus, animals, cells, compositions, documents, drawings, machinery, patent applications, records and reports), which is disclosed by or on behalf of such Party (in such capacity, the "**Disclosing Party**") or its Affiliates to the other Party (in such capacity, the "**Receiving Party**") or its Affiliates or to any of the Receiving Party's or its Affiliates' employees, consultants or subcontractors (collectively, "**Representatives**") in each case under this Agreement or the Material Transfer and Evaluation Agreement, except to the extent that the Receiving Party can demonstrate by contemporaneous written record or other suitable physical evidence that such information, (a) as of the date of disclosure is known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure by or on behalf of the Disclosing Party to the Receiving Party or its Affiliates; (b) as of the date of disclosure is in, or subsequently enters, the public domain through no fault or omission of the Receiving Party or its Affiliates or their respective Representatives; (c) is obtained by the Receiving Party or its Affiliates from a Third Party without breach of any duty and without restriction on disclosure to or from the Disclosing Party; or (d) is independently developed by or for the Receiving Party or its Affiliates without benefit of, reference to or reliance upon any Confidential Information of the Disclosing Party. Except as expressly provided otherwise in this Agreement, (i) Shattuck's Confidential Information shall include, without limitation, Clinical Data, the Shattuck Compound and Shattuck Inventions, and (ii) ImmunoGen's Confidential Information shall include, without limitation, ImmunoGen Compound and ImmunoGen Inventions.

1.13 "**Control**" or "**Controlled**" means, with respect to any Patent Rights, Technology or material, the possession by a Party of the ability to grant a license or sublicense of such Patent Rights or Technology and the rights thereto or to supply such material as contemplated in this Agreement without violating or incurring any obligations under the terms of any arrangement or agreement between such Party or its Affiliates and any Third Party.

1.14 "**Delivery**" has the meaning set forth in Section 8.4.1 and Section 8.4.2.

1.15 "**Disclosing Party**" has the meaning set forth in Section 1.12

1.16 "**Dispute**" has the meaning set forth in Section 25.

1.17 "**Effective Date**" has the meaning set forth in the preamble.

1.18 "**EMA**" has the meaning set forth in the definition of Applicable Law.

1.19 "**Exclusions List**" has the meaning set forth in the definition of Violation.

1.20 "**FDA**" has the meaning set forth in the definition of Applicable Law.

1.21 "**Force Majeure**" has the meaning set forth Section 15.

1.22 "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.

1.23 "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government

or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, in each case enumerated above, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either of the Parties.

1.24 "**HIPAA**" has the meaning set forth in the definition of Applicable Law.

1.25 "**ImmunoGen**" has the meaning set forth in the preamble.

1.26 "**ImmunoGen Background Patents**" has the meaning set forth in Section 10.6.1.

1.27 "**ImmunoGen Class Compound**" means any folate receptor-targeting antibody drug conjugate.

1.28 "**ImmunoGen Compound**" means mirvetuximab soravtansine (IMGN853), a folate receptor alpha (FRα)-targeting antibody drug conjugate.

1.29 "**ImmunoGen Indemnified Party**" has the meaning set forth in Section 13.2.1.

1.30 "**ImmunoGen Inventions**" is defined in Section 10.2.

1.31 "**IND**" means any Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an "**Investigational Medicinal Product Dossier**" filed or to be filed with Regulatory Authorities in the European Union.

1.32 "**Indemnified Party**" has the meaning set forth in Section 13.2.3.

1.33 "**Indemnifying Party**" has the meaning set forth in Section 13.2.3.

1.34 **"Independent Patent Counsel"** means an outside patent counsel reasonably acceptable to both Parties who (and whose firm) is not at the time of the dispute and was not at any time during the five (5)-year period preceding the dispute, performing legal services of any nature for either of the Parties or their respective Affiliates and which did not, at any time, employ either of the Parties' chief patent counsels (or persons with similar responsibilities).

1.35 "**Inventions**" means all Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together in the design or performance of the Study.

1.36 "**Investors**" has the meaning set forth in Section 9.2.

1.37 "**Joint Patent Right**" has the meaning set forth in Section 10.1.3.

1.38 "**Jointly Owned Invention**" has the meaning set forth in Section 10.1.1.

1.39 "**Manufacture**," "**Manufactured**," or "**Manufacturing**" means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.40 "**Manufacturer's Release**" or "**Release**" has the meaning ascribed to such term in the Clinical Quality Agreement.

1.41 "**Manufacturing Site**" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.6.

1.42 "**Material Transfer and Evaluation Agreement**" means the Material Transfer and Evaluation Agreement between the Parties dated as of [***].

1.43 "**NDA**" means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.44 "**Non-Conformance**" means, with respect to a given unit of Compound, [***]

1.45 "**Party**" has the meaning set forth in the preamble.

1.46 "**Patent Rights**" means the rights and interests in and to any and all issued patents and pending patent applications (including inventor's certificates, applications for inventor's certificates, statutory invention registrations, applications for statutory invention registrations, utility models and any foreign counterparts thereof) in any country or jurisdiction, including any and all provisionals, non- provisionals, substitutions, continuations, continuations-in-part, divisionals and other continuing applications, extensions or restorations by existing or future extension or restoration mechanisms, including patent term extension, supplementary protection certificates or the equivalent, renewals, and all letters patent on any of the foregoing, and any and all reissues, reexaminations, extensions, confirmations, registrations and patents of addition on any of the foregoing.

1.47 "**Permitted Use**" has the meaning set forth in Section 3.5.

1.48 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.49 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.

1.50 "**Protocol**" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct; for clarity, "Protocol" solely includes any written documentation that describes the arm of the SL03-OHD-105 Trial involving the ImmunoGen Compound and does not include any other part of the SL03-OHD-105 Trial.

1.51 "**Publisher**" has the meaning set forth in Section 11.1.1.

1.52 "**Receiving Party**" has the meaning set forth in the definition of Confidential Information.

1.53 "**Regulatory Approvals**" means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation and distribution of such Compound in the United States, Europe or other applicable jurisdictions for use in the Study.

1.54 "**Regulatory Documentation**" means, with respect to the Compounds, all submissions to Regulatory Authorities in connection with the development of such Compounds, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include Clinical Data).

1.55 "**Regulatory Authorities**" has the meaning set forth in the definition of Applicable Law.

1.56 "**Related Agreements**" means the Pharmacovigilance Agreement and the Clinical Quality Agreement.

1.57 "**Representatives**" has the meaning set forth in Section 1.12.

1.58 "**Right of Reference**" means the "**right of reference**" defined in 21 CFR 314.3(b), including with regard to Shattuck, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross- reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to the ImmunoGen Compound, only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.

1.59 "**Sample Testing**" means the analyses to be performed by each Party using the applicable Samples, to be described in the Sample Testing Schedule.

1.60 "**Sample Testing Results**" has the meaning set forth in Section 3.5.

1.61 "**Sample Testing Schedule**" is the schedule to be mutually agreed by the Parties following the Effective Date but before any subject is enrolled in the Study.

1.62 "**Samples**" means biological specimens collected from subjects participating in the Study, including urine, blood and tissue samples.

1.63 "**Shattuck**" has the meaning set forth in the preamble.

1.64 "**Shattuck Class Compound**" means any small or large molecule that targets the CD47/ SIRPα axis.

1.65 "**Shattuck Compound**" means Shattuck's proprietary bi-functional fusion protein designated "SL-172154" that targets CD47 on malignant cells and CD40 on immune cells (antigen presenting cells).

1.66 "**Shattuck Indemnified Party**" has the meaning set forth in Section 13.2.2.

1.67 "**Shattuck Inventions**" is defined in Section 10.3.

1.68 "**Specifications**" means, with respect to a given Compound, the set of requirements for such Compound as set forth in the Clinical Quality Agreement.

1.69 "**Study**" means the study arm of the SL03-OHD-105 Trial that is intended to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the concomitant administration of the Shattuck Compound and the ImmunoGen Compound in subjects with ovarian cancer; for clarity, "Study" does not include any other part of the SL03-OHD-105 Trial.

1.70 "**Study Committee**" has the meaning set forth in Section 3.1.

1.71 **"Technology"** means, collectively, all inventions, discoveries, improvements, trade secrets and proprietary methods or material, whether or not patentable, including, without limitation, macromolecular sequences, data, formulations, processes, techniques, know-how and results (including negative results).

1.72 "**Term**" has the meaning set forth in Section 6.1.

1.73 "**Territory**" means anywhere in the world.

1.74 "**Third Party**" means any Person or entity other than ImmunoGen, Shattuck or their respective Affiliates.

1.75 "**Third Party Claim**" has the meaning set forth in Section 13.2.1.

1.76 "**Violation**" means that a Party or any of its officers or directors or any other personnel (or other permitted agents of such Party performing activities hereunder) has been: (i) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (ii) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); or (iii) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) ((i), (ii) and (iii) collectively, the "**Exclusions Lists**").

2 Conduct of the Study; Scope of the Agreement.

2.1 *Study*. Shattuck is the sponsor of the Study under its existing IND for the Shattuck Compound with a Right of Reference to the IND of the ImmunoGen Compound as further described in Section 4.2. In no event shall Shattuck file an additional IND for the Study without ImmunoGen's prior written consent. Shattuck shall ensure that the Study is performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP. Subject to the terms of this Agreement (including Section 2.4 and Article 6), Shattuck has sole authority over the design, conduct and control of the Study; [***].

2.2 *Compound Commitments*. ImmunoGen agrees to Manufacture (or have Manufactured) and supply the ImmunoGen Compound in sufficient quantity and on a timely basis for purposes of the Study in accordance with Article 8, and ImmunoGen hereby represents and warrants to Shattuck that, at the time of Delivery of the ImmunoGen Compound, such ImmunoGen Compound shall have been Manufactured and supplied in compliance with: (i) the Specifications for the ImmunoGen Compound; (ii) the Clinical Quality Agreement; and (iii) all Applicable Law. Shattuck agrees to Manufacture (or have Manufactured) and supply the Shattuck Compound for purposes of the Study in accordance with Article 8, and Shattuck hereby represents and warrants to ImmunoGen that, at the time of Delivery of the Shattuck Compound, such Shattuck Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Shattuck Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (*provided* that, for clarity, Shattuck shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 4.2).

2.3 *Subcontracting*. Each Party shall have the right to subcontract any portion of its obligations hereunder: (i) to its own Affiliates, without the other Party's written consent; or (ii) to Third Parties with the other Party's consent; *provided* that no consent shall be necessary for either Party's delegation to or use of contract research organizations or other Third Parties that (A) are conducting clinical trials of such Party's Compound and are set forth

in the Protocol as performing such Study activities, or (B) are conducting Sample Testing for such Party, or (C) are Manufacturing the Parties' respective Compounds. In any event, each Party shall remain solely and fully liable for the performance of its Affiliates and subcontractors to which such Party delegates the performance of its obligations under this Agreement. Each Party shall ensure that each of its Affiliates and subcontractors performs such Party's obligations pursuant to the terms of this Agreement. Each Party shall use [***] to obtain and maintain copies of documents relating to the obligations performed by such Affiliates and subcontractors that are required to be provided to the other Party under this Agreement.

2.4 *Protocol*. Shattuck shall provide a draft of the Protocol (and any subsequent revisions thereof) to ImmunoGen for ImmunoGen's review and comment prior to submitting the Protocol to any Regulatory Authority or institutional review boards, and in no event shall Shattuck submit such Protocol to a Regulatory Authority or institutional review boards unless such Protocol has been approved as set forth in this Section 2.4. Shattuck shall consider in good faith any changes to the draft of the Protocol reasonably requested by ImmunoGen; *provided* that Shattuck shall incorporate any changes requested by ImmunoGen with respect to the ImmunoGen Compound. Unless expressly otherwise set forth in this Agreement, Shattuck shall have the final decision-making authority with respect to the contents of the Protocol except that: (a) all revisions to the Protocol shall be disclosed to ImmunoGen by Shattuck in writing prior to their implementation and (b) any material changes to any draft of the Protocol (other than relating solely to the Shattuck Compound) from the draft of the Protocol previously provided to ImmunoGen, any material changes (other than relating solely to the Shattuck Compound) to the approved final Protocol, and any changes (whether or not material) relating to the ImmunoGen Compound, shall each require ImmunoGen's prior written consent prior to being implemented. Any such proposed changes will be sent in writing to ImmunoGen's Alliance Manager. ImmunoGen will have [***] Business Days following receipt of Shattuck's requested changes to indicate that it withholds its consent to any such change; if no comments are provided by ImmunoGen within the given review period, such changes shall be deemed acceptable to ImmunoGen. Notwithstanding anything to the contrary contained herein, the dose and dosing regimen for the Shattuck Compound and ImmunoGen Compound will require the mutual written consent of the Parties prior to implementation in the Protocol.

2.5 *Relationship*. Other than as expressly set forth in this Agreement, including Sections 10.1.2 and 10.4 nothing in this Agreement shall (i) prohibit either Party from performing clinical studies other than the Study relating to its own Compound, either individually or in combination with any other compound or product, in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to any Compound. Notwithstanding anything in this Agreement to the contrary, but subject to Sections 3.5, 10.4 and 10.1.2, each Party acknowledges and agrees that the other Party may have present or future business activities or opportunities, including business activities or opportunities with Third Parties, involving ImmunoGen Class Compounds, in the case of Shattuck, or Shattuck Class Compounds, in the case of ImmunoGen, or other similar products, programs, technologies or processes. Accordingly, each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, including ImmunoGen Class Compound or Shattuck Class Compounds, *provided* that the Clinical Data, Confidential Information, Jointly Owned Inventions and Sample Testing Results are not used or disclosed in connection therewith in violation of Section 3.5 or 10.4 or Article 9 or Article 10 of this Agreement.

2.6 *Anti-Bribery/Anti-Corruption*. Each Party agrees, on behalf of itself and its officers, directors, employees, Affiliates, agents and representatives, that in connection with this Agreement and the performance of its obligations hereunder: (i) it will comply with its own ethical business practices policy and shall conduct its Study-related activities in accordance with Applicable Law including the Anti-Bribery and Anti-Corruption Laws; (ii) it will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give or authorize the giving of anything of value to: (a) any Government Official in order to influence official action; (b) any person (whether or not a Government Official) (I) to influence that person to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (II) to reward the person for acting improperly, or (III) where that person would be acting improperly by receiving the thing of value; or any other person while knowing or having reason to know that all or any portion of the money or thing of value will be offered, promised or given to a Government Official in order to influence official action or to any person to influence that person to act improperly; and (iii) it will not directly or indirectly solicit, receive or agree to accept any payment or anything else of value in violation of the Anti-Bribery and Anti-Corruption Laws.

3. Governance; Reporting.

3.1 *Study Committee*. Promptly after the Effective Date, the Parties shall form a study committee (the "**Study Committee**"), which shall have responsibility of coordinating all regulatory and other activities under, and pursuant to, this Agreement. Each Party shall designate an alliance manager (the "**Alliance Manager**") who shall serve as the primary point of contact for any issues arising under this Agreement and shall be responsible for implementing and coordinating activities, and facilitating the exchange of information between the Parties with respect to the Study. Each Party's Alliance Manager shall be a member of the Study Committee along with four (4) other members, two (2) selected by each Party. Each Party can change its members on the Study Committee, including its Alliance Manager, by written notice to the other Party. The Study Committee shall meet as soon as practicable after the Effective Date and then quarterly, and more often if agreed by the Parties, to provide an update on the progress of the Study. The Study Committee may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications equipment. Prior to any such meeting, the Shattuck Alliance Manager shall provide an update in writing to the ImmunoGen Alliance Manager, which update shall contain information about the overall progress of the Study, recruitment status, interim analysis (if results available), final analysis and other information relevant to the conduct of the Study. The Alliance Managers may bring to the attention of the Study Committee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. In the event that an issue arises and the Alliance Managers cannot or do not, after good faith efforts, reach agreement on such issue, the issue shall be escalated as set forth in Section 25.

3.2 *Documentation*. Shattuck shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Subject to the limitations set forth in Section 4.2 hereof regarding CMC data relating to the Shattuck Compound, Shattuck shall provide to ImmunoGen all Study information and documentation reasonably requested by ImmunoGen to enable ImmunoGen to comply with any of its legal and/or regulatory obligations, or any request by any Regulatory Authority related to the ImmunoGen Compound, (ii) determine whether the Study has been performed in accordance with this Agreement and (iii) exercise its rights under this Agreement.

3.3 *Clinical Data*. Shattuck shall provide to ImmunoGen quarterly reports about the progress of the Study, including summaries of all Clinical Data, except that such quarterly reports will not include raw data. For clarity, raw data will not be provided to ImmunoGen until it has been cleaned following database lock. Clinical Data associated with pharmacokinetics shall be provided to ImmunoGen annually. A complete copy of the Clinical Data shall be provided to ImmunoGen no later than [***] days following completion of the Final Study Report. Shattuck shall ensure that all patient authorizations and consents required under HIPAA, the EU Data Protection Directive, or any successor directive (to the extent any part of the Study is done in Europe) or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with ImmunoGen.

3.4 *Final Study Report*. Shattuck shall provide ImmunoGen with (i) an electronic draft in near- final form of the portion of the final study report relating to the Study, for ImmunoGen to provide comments to Shattuck and (ii) a final version of the portion of the final study report relating to the Study (the "**Final Study Report**") promptly following completion thereof. Shattuck shall consider in good faith any comments provided by Shattuck within [***] days of ImmunoGen's receipt of the electronic draft referred to above for inclusion in the Final Study Report and shall not include any statements relating to the ImmunoGen Compound which have not been approved by ImmunoGen; provided that if no comments are provided by ImmunoGen within the given review period, such draft shall be deemed acceptable to ImmunoGen.

3.5 *Samples*. As between ImmunoGen and Shattuck, all Samples shall remain the property of Shattuck. Shattuck shall provide Samples to ImmunoGen as specified in the Protocol and each Party shall solely test Samples in accordance with the Sample Testing Schedule and the Protocol. Each Party shall own all data arising from any testing of the Samples (such data, the "**Sample Testing Results**") conducted by or on behalf of such Party and shall promptly provide the results of such testing to the other Party or as otherwise agreed by the Study Committee. Each Party may freely use the Sample Testing Results that it owns but may not disclose any unpublished Sample Testing Results owned by the other Party to a Third Party except for the purposes of (i) seeking Regulatory Approval for the use of its respective Compound in the Combination and (ii) filing and prosecuting patent applications for Jointly Owned Inventions in accordance with Article 10 (collectively, the "**Permitted Use**"), unless otherwise mutually agreed in writing by the Parties.

4 Regulatory; Compliance with Laws.

4.1 *Informed Consent*. Shattuck shall prepare the patient informed consent form for the Study (which shall include provisions regarding the use of Samples as described in Section 3.5) in consultation with ImmunoGen

with respect to the portions related to the ImmunoGen Compound (it being understood and agreed that the portion of the informed consent form relating to the Sample testing of the ImmunoGen Compound shall be provided to Shattuck by ImmunoGen). Any proposed changes to such form that relate to the ImmunoGen Compound, including Sample testing of the ImmunoGen Compound, shall be subject to ImmunoGen's review and written consent. Any such proposed changes will be sent in writing to ImmunoGen's Alliance Manager. ImmunoGen will have [***] Business Days following receipt of Shattuck's requested changes to indicate that it withholds its consent to any such change; if no comments are provided by ImmunoGen within the given review period, such changes shall be deemed acceptable to ImmunoGen.

4.2 *Regulatory Matters*. Shattuck shall ensure that all directions from any Regulatory Authority, ethics committees and/or institutional review boards with jurisdiction over the Study are followed. Further, Shattuck shall ensure that all Regulatory Approvals from any Regulatory Authority, ethics committees and/or institutional review boards with jurisdiction over the Study are obtained prior to initiating performance of the Study. ImmunoGen shall have the right (but no obligation) to participate in any discussions with a Regulatory Authority regarding matters related to the ImmunoGen Compound. ImmunoGen shall provide to Shattuck a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to its Compound; provided, however, if there is any inquiry from a Regulatory Authority regarding ImmunoGen's CMC data, then ImmunoGen shall use [***] to disclose any such CMC data requested directly to the applicable Regulatory Authority in a timely manner, and in any event within the timeframe required by such Regulatory Authority. ImmunoGen shall authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate ImmunoGen Compound INDs and clinical trial authorizations to provide data access to Shattuck sufficient to support conduct of the Study.

4.3 *Debarred Personnel; Exclusion Lists*. Neither Party shall employ or subcontract with any Person or Third Party that is excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs for the performance of the Study or any other activities under this Agreement or the Related Agreements. Each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Study or other activities under this Agreement or the Related Agreements and that such Party has, as of the Effective Date, screened itself, and its officers and directors, against the Exclusions Lists and that it has informed the other Party whether it or any of its officers or directors has been in Violation. Each Party shall promptly notify the other Party in writing if any such suspension, proposed debarment, debarment or Violation occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment, debarred or in Violation, promptly remove such Person from performing activities, function or capacity related to the Study or otherwise related to activities under this Agreement or the Related Agreements, and the other Party shall have the right to terminate this Agreement in accordance with the terms hereof if any such suspension, proposed debarment, debarment or Violation involves the first Party or its officers or directors.

5 Adverse Event Reporting.

Shattuck will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for the Study. The Parties will execute a pharmacovigilance agreement ("**Pharmacovigilance Agreement**") prior to the initiation of clinical activities under the Study to ensure the exchange of relevant safety data within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Shattuck Compound and ImmunoGen Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities.

6 Term and Termination.

6.1 *Term*. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until the delivery of the Final Study Report unless earlier terminated by either Party pursuant to this Agreement (such period of time, the "**Term**"). Early termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

6.2 *ImmunoGen Termination Right for Safety*. In the event that ImmunoGen in good faith believes that the ImmunoGen Compound is being used in the Study in an unsafe manner or that the Study may unreasonably affect patient safety and, in either case, notifies Shattuck in writing of the grounds for such belief, and (i) Shattuck fails to (a) promptly incorporate changes into the Protocol requested by ImmunoGen to address such issue or (b) otherwise reasonably and in good faith address such issue or (ii) such issue cannot reasonably be addressed, ImmunoGen may immediately terminate this Agreement and the supply of the ImmunoGen Compound upon written notice to Shattuck.

6.3 *Material Breach*. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach is not cured within [***] days after receipt of written notice thereof from the non-breaching Party, then the notifying Party may terminate this Agreement effective after the expiration of such [***] day period.

6.4 *Mutual Termination Right for Patient Safety*. If either Party determines in good faith, based on a review of the Clinical Data, Sample Testing Results or other Study-related Technology or other information, that the Study poses an imminent danger to patients, such Party may terminate this Agreement immediately upon written notice to the other Party.

6.5 *Mutual Termination Right Due to Regulatory Action; Other Reasons*. Either Party may terminate this Agreement immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that causes it to be unreasonable for, or otherwise prevents, the terminating Party from supplying its Compound for purposes of the Study. Additionally, either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party in the event that it withdraws any applicable Regulatory Approval for its Compound or discontinues development of its Compound for any reason.

6.6 *Termination by Shattuck*. Shattuck may terminate this Agreement upon sixty (60) days' prior written notice to ImmunoGen for any reason; *provided* that if the Study is underway at the time of such notice, such termination of this Agreement shall only be effective sixty (60) days following the Parties' mutual agreement on a written plan for the winddown or termination of the Study, such plan to prioritize patient safety and outcomes and to ensure compliance with Applicable Law. The Parties shall comply with such a termination plan and the obligation to so comply shall survive any termination of this Agreement.

6.7 *Return of ImmunoGen Compound*. In the event that this Agreement is terminated, or in the event Shattuck remains in possession (including through any Affiliate or subcontractor) of ImmunoGen Compound provided by or on behalf of ImmunoGen at the time this Agreement expires, Shattuck shall, at ImmunoGen's sole discretion, promptly either return or destroy all unused ImmunoGen Compound pursuant to ImmunoGen's instructions; provided, however, a Study site may destroy ImmunoGen Compound in accordance with Applicable Law upon termination or expiration of this Agreement if Applicable Law or such Study site's policies require that ImmunoGen Compound be destroyed. If ImmunoGen requests that Shattuck destroy the unused ImmunoGen Compound, Shattuck shall provide written certification of such destruction.

6.8 *Survival*. The provisions of this Section 6.8 and Section 10.5, 4.2, 6.6, 6.7, 6.9, 8.7.2a),8.7.2c), 8.7.3, 8.8, 8.9, 8.10, 8.12, 8.13, 11.1, and Articles 1, 9, 10 (except for 10.6), 13 and 16 - 29 shall survive the expiration or termination of this Agreement.

6.9 *Confidential Information*. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Jointly Owned Inventions) furnished to the Receiving Party by the Disclosing Party, except that the Receiving Party shall have the right to retain one copy for record-keeping purposes.

7 Costs of Study.

The Parties agree that (i) each Party shall provide its Compound, at its cost, for use in the Study, as described in Article 8 below and (ii) each Party will be responsible for its own internal costs and expenses to support the Study and the costs of any Sample Testing conducted by such Party in connection with the Study, [***]. Shattuck shall bear all other costs associated with the conduct of the Study, except that ImmunoGen will reimburse Shattuck Two Million Dollars ($2,000,000) of the costs incurred by Shattuck. Shattuck will invoice ImmunoGen for such costs [***] of the Study. ImmunoGen will pay all invoices issued in accordance with the terms of this Agreement within [***] days of receipt.

8 Supply and Use of the Compounds.

8.1 *Supply of the Compounds*. Subject to the terms and conditions of this Agreement, ImmunoGen and Shattuck will each use [***] to supply, or cause to be supplied, such quantities of its Compound in accordance with

the delivery schedule to be mutually agreed by the Parties following the Effective Date to begin enrollment of subjects into the Study as soon as practicable following the FDA's approval of ImmunoGen's biologic license application for the ImmunoGen Compound; *provided* that the quantities and applicable timelines for Delivery of (i) the Shattuck Compound supplied hereunder shall be subject to Shattuck's approval, in its sole discretion and (ii) the ImmunoGen Compound supplied hereunder shall be subject to ImmunoGen's approval, in its sole discretion. Each Party shall also provide to the other Party a contact person for the supply of its Compound under this Agreement. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound as contemplated by this Agreement.

8.2 *Clinical Quality Agreement*. Within [***] days from the Effective Date of this Agreement, the Parties shall use [***] to enter into a quality agreement that shall address and govern issues related to the quality of clinical drug supply to be supplied by the Parties for use in the Study ("**Clinical Quality Agreement**"). The Clinical Quality Agreement shall, among other things: (i) detail classification of any Compound found to have a Non-Conformance; (ii) include criteria for Manufacturer's Release and related certificates and documentation; (iii) include criteria and timeframes for acceptance of ImmunoGen Compound; (iv) include procedures for the resolution of disputes regarding any Compounds found to have a Non-Conformance; and (v) include provisions governing the recall of Compounds. ImmunoGen will not be obliged to ship ImmunoGen Compound to Shattuck until the Clinical Quality Agreement has been finalized and executed by the Parties. If, within [***] days from the Effective Date of this Agreement (or such longer period as the Parties may mutually agree upon), the Parties have not entered into the Clinical Quality Agreement, either Party may terminate this Agreement upon written notice to the other Party.

8.3 *Minimum Shelf-Life Requirements*. Each Party shall use [***] to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the Study requirements.

8.4 *Provision of Compounds*.

8.4.1 ImmunoGen will deliver the ImmunoGen Compound [***] to Shattuck's, or its designee's, location as specified by Shattuck ("**Delivery**" with respect to such ImmunoGen Compound). Title and risk of loss for the ImmunoGen Compound shall transfer from ImmunoGen to Shattuck [***]. All costs associated with the subsequent transportation, warehousing and distribution of ImmunoGen Compound shall be borne by Shattuck. Shattuck will, or will cause its designee to: (i) take delivery of the ImmunoGen Compound supplied hereunder; (ii) perform the acceptance procedures allocated to it under the Clinical Quality Agreement; and (iii) subsequently label and pack the ImmunoGen Compound (in accordance with Section 8.5) in accordance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement; and (iv) provide, from time to time at the reasonable request of ImmunoGen, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by ImmunoGen, and usage and inventory reconciliation documentation related to the ImmunoGen Compound.

8.4.2 Shattuck is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Shattuck Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the Shattuck Compound supplied hereunder. Shattuck shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement. For purposes of this Agreement, the "**Delivery**" of a given quantity of the Shattuck Compound shall be deemed to occur when such quantity is packaged for shipment to a Study site.

8.5 *Labeling and Packaging; Use, Handling and Storage*.

8.5.1 The Parties' obligations with respect to the labeling and packaging of the Compounds are as set forth in the Clinical Quality Agreement.

8.5.2 With respect to any ImmunoGen Compound provided by or on behalf of ImmunoGen, Shattuck shall (i) use the ImmunoGen Compound solely for purposes of performing the Study; (ii) not use the ImmunoGen Compound in any manner that is inconsistent with this Agreement or for any commercial purpose; and (iii) label, use, store, transport, handle and dispose of the ImmunoGen Compound in compliance with Applicable Law and the Clinical Quality Agreement, as well as all written instructions of ImmunoGen that do not conflict with Applicable Law or the Clinical Quality Agreement. Shattuck shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the ImmunoGen Compound, and in particular shall not analyze the ImmunoGen Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Quality Agreement.

8.6 *Product Specifications; Manufacturing Site*. A certificate of analysis shall be provided with each shipment of the ImmunoGen Compound to Shattuck. Upon request, Shattuck shall provide ImmunoGen with a certificate of analysis covering each shipment of Shattuck Compound used in the Study. Each Party may make changes from time to time to its Compound or the Manufacturing Site; provided that such changes shall be in accordance with the Clinical Quality Agreement or as otherwise mutually agreed by the Parties.

8.7 *Product Testing; Noncompliance*.

8.7.1 *After Manufacturer's Release*. After Manufacturer's Release of the ImmunoGen Compound and concurrently with Delivery of the Compound to Shattuck, ImmunoGen shall provide Shattuck with such certificates and documentation as are described in the Clinical Quality Agreement. Shattuck shall, within the time defined in the Clinical Quality Agreement, perform (i) with respect to the ImmunoGen Compound, the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement, and (ii) with respect to the Shattuck Compound, the testing and release procedures allocated to it under the Clinical Quality Agreement. Shattuck shall be solely responsible for taking all steps necessary to determine that ImmunoGen Compound or Shattuck Compound, as applicable, is suitable for release before making such ImmunoGen Compound or Shattuck Compound, as applicable, available for human use, and ImmunoGen shall provide cooperation or assistance as reasonably requested by Shattuck in connection with such determination with respect to the ImmunoGen Compound. Upon Delivery, Shattuck shall be responsible for storage and maintenance of the ImmunoGen Compound until it is tested and/or released, which storage and maintenance shall be in compliance with (a) the Specifications for the ImmunoGen Compound, the Clinical Quality Agreement and Applicable Law, and (b) any specific storage and maintenance requirements as may be provided in writing by ImmunoGen from time to time that do not conflict with Applicable Law or the Clinical Quality Agreement. Shattuck shall be responsible for any failure of the ImmunoGen Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to Shattuck hereunder.

8.7.2 *Non-Conformance.*

a) In the event that either Party becomes aware that any Compound may have a Non- Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.7.1), such Party shall immediately notify the other Party in accordance with the procedures of the Clinical Quality Agreement. The Parties shall investigate any such Non-Conformance in accordance with Section 8.8 (*Investigations*) and any discrepancy between them shall be resolved in accordance with Section 8.7.3.

b) In the event that any proposed or actual shipment of the ImmunoGen Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Shattuck, then unless otherwise agreed to by the Parties, ImmunoGen shall replace such ImmunoGen Compound as is found to have a Non-Conformance (with respect to ImmunoGen Compound that has not yet been administered in the course of performing the Study) as soon as reasonably possible. Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Shattuck with respect to any ImmunoGen Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such ImmunoGen Compound as set forth in this Section 8.7.2b), (ii) indemnification under Section 13.2.2 (to the extent applicable) and (iii) termination of this Agreement pursuant to Section 6.6 or 6.3 (to the extent applicable, but subject to the applicable cure period set forth therein). In the event ImmunoGen Compound is lost or damaged by Shattuck after Delivery, ImmunoGen shall provide additional ImmunoGen Compound (if available for the Study) to Shattuck; *provided* that Shattuck shall reimburse ImmunoGen for the actual internal and out-of pocket costs reasonably incurred for such replaced ImmunoGen Compound; and *provided* further that ImmunoGen shall have no obligation to so provide additional ImmunoGen Compound more than once. Except as set forth in the foregoing sentence, ImmunoGen shall have no obligation to provide replacement ImmunoGen Compound for any ImmunoGen Compound supplied hereunder other than such ImmunoGen Compound as has been agreed or determined to have a Non- Conformance at the time of Delivery to Shattuck.

c) Shattuck shall be responsible for, and ImmunoGen shall have no obligations or liability with respect to, any Shattuck Compound supplied hereunder that is found to have a Non- Conformance.

8.7.3 *Resolution of Discrepancies*. Disagreements regarding any determination of Non- Conformance of the ImmunoGen Compound shall be resolved in accordance with the provisions of the Clinical Quality Agreement.

8.8 *Investigations*. The process for investigations of any Non-Conformance shall be handled in accordance with the Clinical Quality Agreement.

8.9 *Records; Audit Rights*. Shattuck shall keep complete and accurate records pertaining to its use and disposition of ImmunoGen Compound (including its storage, shipping (cold chain) and chain of custody activities)

and, upon reasonable prior written request of ImmunoGen but no less than [***] Business Days, shall make such records open to review by ImmunoGen during normal business hours and at such places where such records are customarily kept for the purpose of conducting investigations for the determination of ImmunoGen Compound safety and/or efficacy and Shattuck's compliance with this Agreement with respect to the ImmunoGen Compound.

8.10 *Quality*. Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement. In the event that there is an inconsistency between this Agreement and the Clinical Quality Agreement, this Agreement shall govern, except for those quality related matters that are specifically set forth in the Clinical Quality Agreement and not in this Agreement.

8.11 *Quality Control*. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the Clinical Quality Agreement.

8.12 *Audits and Inspections*. The Parties' audit and inspection rights related to this Agreement shall be governed by the terms of the Clinical Quality Agreement.

8.13 *Recalls*. Recalls of the Compounds shall be governed by the terms of the Clinical Quality Agreement.

9 Confidentiality.

9.1 *Confidentiality Obligations*. ImmunoGen and Shattuck each recognizes that the other Party's Confidential Information constitutes highly valuable assets of such other Party. ImmunoGen and Company each agrees that, subject to Section 9.2 hereof, during the Term and for an additional [***] thereafter, (i) it will not disclose, and will cause its Affiliates not to disclose, any Confidential Information of the other Party and (ii) it will not use, and will cause its Affiliates not to use, any Confidential Information of the other Party, in either case, except as expressly permitted hereunder. Without limiting the generality of the foregoing, each Party shall take such action, and shall cause its Affiliates to take such action, to preserve the confidentiality of the other Party's Confidential Information as such Party would customarily take to preserve the confidentiality of its own confidential information and shall, in any event, use at least reasonable care to preserve the confidentiality of the other Party's Confidential Information.

9.2 *Limited Disclosure*. Each Receiving Party shall be entitled to disclose the Disclosing Party's Confidential Information to its Affiliates and their respective Representatives to enable the Receiving Party to exercise its rights (including ImmunoGen's rights under Section 10.4) or to carry out its responsibilities under this Agreement, *provided* that such disclosure shall only be made to Persons who are bound by written obligations at least as stringent as those described in Section 9.1 hereof, and Receiving Party shall be responsible for the compliance of its Affiliates and its and their Representatives with the obligations hereunder. In addition, the Receiving Party may disclose the Disclosing Party's Confidential Information to the extent such disclosure (i) is reasonably necessary to file, prosecute or defend litigation related to Patent Rights or (ii) is required by Applicable Law, *provided* that the Receiving Party shall (A) if legally permissible, provide the Disclosing Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (B) if requested by the Disclosing Party, cooperate in all reasonable respects with the Disclosing Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the Disclosing Party's expense, and (C) use [***] to incorporate the comments of the Disclosing Party in any such disclosure or request for confidential treatment or a protective order. Notwithstanding the foregoing, each Party may disclose the terms of this Agreement to (w) actual or potential lenders or investors of such Party, (x) actual or potential acquirers of such Party, (y) actual or potential strategic partners that are or may be a licensee of intellectual property of the disclosing Party relating to the subject matter of this Agreement, and (z) its legal, accounting, tax and other advisors (collectively, "**Investors**"), in each case subject to written obligations of confidentiality and non-use customary for such type of Investor; provided, however, that the disclosing Party shall be responsible for the compliance of its Investors with the confidentiality obligations imposed hereunder.

9.3 *Representatives*. ImmunoGen and Shattuck each hereby represents and warrants that all of its and its Affiliates' Representatives who participate in the activities contemplated by this Agreement or who otherwise have access to Confidential Information of the other Party are or will, prior to their participation or access, be bound by written obligations to maintain such Confidential Information in confidence and not to use such information except as

expressly permitted hereunder. Each Party agrees to be responsible for the compliance of its and its Affiliates' Representatives with the obligations hereunder.

9.4 *Inventions*. Notwithstanding the foregoing, (i) Inventions that constitute Confidential Information and are Jointly Owned Inventions, shall constitute the Confidential Information of both Parties and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10 and 11 and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10 and 11.

9.5 *Personal Identifiable Data*. All Confidential Information containing personal identifiable data shall be handled in accordance with all Applicable Law, including data protection and privacy laws, rules and regulations applicable to such data.

10 Intellectual Property; Data.

10.1 *Joint Ownership and Prosecution.*

10.1.1 Subject to Section 10.2 and Section 10.3, all rights to [***] (each, a "**Jointly Owned Invention**") shall belong jointly to ImmunoGen and Shattuck. Shattuck hereby assigns to ImmunoGen an undivided one-half interest in, to and under the Jointly Owned Inventions that are invented or created by Shattuck or by Persons having an obligation to assign such rights to Shattuck. ImmunoGen hereby assigns to Shattuck an undivided one-half interest in, to and under any Jointly Owned Inventions that are invented or created by ImmunoGen or by Persons having an obligation to assign such rights to ImmunoGen. ImmunoGen and Shattuck shall each be entitled to use the Jointly Owned Inventions in accordance with Section 10.1.2. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention to practice or license such Jointly Owned Invention in such countries, (i) Shattuck hereby grants to ImmunoGen a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Shattuck's right, title and interest in and to all Jointly Owned Inventions to use such Inventions, and (ii) ImmunoGen hereby grants to Shattuck a perpetual, irrevocable, non- exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under ImmunoGen's right, title and interest in and to all Jointly Owned Inventions to use such Inventions. For clarity, the terms of this Agreement do not provide ImmunoGen or Shattuck with any rights, title or interest or any license to the other Party's intellectual property except as necessary to conduct the Study and as expressly provided under this Agreement, including as set forth in Section 10.6.

10.1.2 Each Party shall have the right to freely exploit each Jointly Owned Invention, without accounting to or any other obligation to the other Party; *provided*, *however*, that during the Term, (i) Shattuck covenants and agrees that it and its [***] and (ii) ImmunoGen covenants and agrees that it and its Affiliates [***].

10.1.3 If both Parties desire to file a Patent Right in respect of any Jointly Owned Invention ("**Joint Patent Right**"), the Parties will do so at [***] expense and consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of such Joint Patent Right as will reasonably and properly be required. Shattuck will control prosecution of any such Joint Patent Right, provided that no Joint Patent Right will claim or disclose any of ImmunoGen's Confidential Information without ImmunoGen's prior written consent. Preparation, filing and prosecution of a Joint Patent Right will be through counsel acceptable to both Parties. The Parties will instruct such counsel to provide Shattuck and ImmunoGen with (i) copies of all office actions and correspondence and communications from relevant patent offices issued in connection with a Joint Patent Right; and (ii) as much prior notice as practicable to review and comment on any communication with or submission to any patent office regarding a Joint Patent Right. In the event that Shattuck and ImmunoGen provide conflicting instructions that cannot be resolved, both Parties agree that such counsel will be instructed to proceed with the instructions provided by Shattuck to the extent such instructions would lead solely to disclosure of the Combination and the pursuit of patent claims directed thereto. If only one Party desires to file a Joint Patent Right (and the other Party confirms in writing that it does not desire to join in such filing, which it will do promptly upon the request of the other Party), then the filing Party may file such Joint Patent Right at its sole expense solely to the disclosure of the Combination and claims directed thereto, provided that such Joint Patent Right will not claim or disclose any Confidential Information of the other Party without such Party's prior written consent. In the event that either Shattuck or ImmunoGen decides to cease prosecution and/or maintenance of any Joint Patent Right, the Party ceasing prosecution and/or maintenance of any Joint Patent Right will provide the other Party with the opportunity, at such other Party's sole discretion and expense, to continue prosecution or maintenance of such Joint Patent Right, provided, however, that any subsequent filing (including any claim amendments) is limited solely to the disclosure of

the Combination and the pursuit of patent claims directed thereto. For purposes of this Section 10.1.3, "prosecution" includes defense of invalidity, declaratory judgment, revocation, reexamination, nullity, opposition, or other proceeding in which the validity of a Joint Patent Right is challenged in an administrative or legal proceeding, other than such administrative or legal proceeding that is related to an infringement action brought by a Party or a declaratory action defended by a Party. If the Parties elect to file a Patent Right in respect of any Jointly Owned Invention and "Joint Program Technology" (as defined in the Material Transfer and Evaluation Agreement), such Patent Right will be a Joint Patent Right under this Agreement as opposed to a Patent Right claiming "Joint Program Technology" under the Material Transfer and Evaluation Agreement.

10.2 *Inventions Owned by ImmunoGen*. Notwithstanding Section 10.1, the Parties agree that all rights to [***] ("**ImmunoGen Inventions**"). ImmunoGen shall be entitled to file in its own name relevant patent applications and to own resultant Patent Rights for any ImmunoGen Invention. For the avoidance of doubt, any Invention generically encompassing the ImmunoGen Compound or other ImmunoGen Class Compound (and not the Combination) within its scope, even where the ImmunoGen Compound is not disclosed *per se*, is an ImmunoGen Invention. Shattuck hereby assigns its right, title and interest to any and all ImmunoGen Inventions to ImmunoGen.

10.3 *Inventions Owned by Shattuck*. Notwithstanding Section 10.1, the Parties agree that all rights to [***] ("**Shattuck Inventions**"). Shattuck shall be entitled to file in its own name relevant patent applications and to own resultant Patent Rights for any Shattuck Invention. For the avoidance of doubt, any Invention generically encompassing the Shattuck Compound or another Shattuck Class Compound (and not the Combination) within its scope, even where the Shattuck Compound or other Shattuck Class Compound is not disclosed per se, is a Shattuck Invention. ImmunoGen hereby assigns its right, title and interest to any and all Shattuck Inventions to Shattuck.

10.4 *Ownership and Use of Clinical Data*. All Clinical Data, including raw data from the electronic database and results, generated under this Agreement shall be owned by Shattuck. Shattuck shall grant and hereby grants ImmunoGen a non-exclusive, worldwide, irrevocable, perpetual, fully paid-up, royalty-free license to use the Clinical Data for research and development of the ImmunoGen Compound (including any product, or combination therapy including such), with the right to sublicense such license to a third party licensee of the ImmunoGen Compound (including any product, or combination therapy including such), subject to the obligations of confidentiality and restrictions on publications applicable to ImmunoGen hereunder. Notwithstanding the foregoing, ImmunoGen may use the Clinical Data in accordance with this Agreement for regulatory submissions or in connection with discussions with Regulatory Authorities in any jurisdiction. Shattuck shall be responsible for maintaining the Clinical Data in a validated system. Notwithstanding the foregoing, during the Term, (i) Shattuck covenants and agrees that it and its Affiliates may not use the Clinical Data, directly or indirectly, to research, develop or commercialize an ImmunoGen Class Compound other than the ImmunoGen Compound in combination with a Shattuck Class Compound, and (ii) ImmunoGen covenants and agrees that it and its Affiliates may not use the Clinical Data, directly or indirectly, to research, develop or commercialize a Shattuck Class Compound other than the Shattuck Compound in combination with an ImmunoGen Class Compound, in each case (i) and (ii), except as necessary to comply with Applicable Law or as may be necessary to comply with its internal policies and procedures with respect to pharmacovigilance and adverse event reporting. For clarity, the foregoing sentence shall not restrict Shattuck or ImmunoGen from otherwise researching, developing or commercializing an ImmunoGen Class Compound or Shattuck Class Compound, respectively, without the use of the Clinical Data.

10.5 *Licensing*. Other than as set forth in Sections 2.5, 3.5, 10.1.2 and 10.4 nothing in this Agreement shall prohibit or restrict a Party from licensing, assigning or otherwise transferring to an Affiliate or Third Party its Compound and the related Confidential Information, Jointly Owned Inventions or Sample Testing Results; [***].

10.6 *Unblocking License for Study; No Other Rights*.

10.6.1 *ImmunoGen License to Shattuck*. ImmunoGen hereby grants to Shattuck [***], solely for the purpose of conducting the Study *provided, however,* that in no event shall Shattuck have the right to use [***] to commercialize the ImmunoGen Compound or any ImmunoGen Class Compound, including as part of a product.

10.6.2 *No Other Rights*. For clarity, the terms of this Section 10.6 do not provide Shattuck or ImmunoGen with any rights, title or interest or any license to the other Party's intellectual property rights [***] except as necessary to conduct the Study.

10.7 *Third Party Intellectual Property Rights*. Neither Party makes any representation or warranty, nor shall either Party have any obligation or financial responsibility to the other Party, with respect to any intellectual property rights in and to any Invention owned or co-owned by a Third Party (*e.g*., a site or investigator involved in the Study), except to the extent such Party Controls such Invention.

11 Publications; Press Releases.

11.1 *Publication*. Each Party shall use [***] to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:

11.1.1 Subject to the terms of this Section 11.1.1, Shattuck and/or any Study site or Study investigator ("**Publisher**") is free to publish in scientific journals or other scholarly media the Clinical Data; however, any such publication will not include ImmunoGen's Confidential Information without the prior written consent of ImmunoGen. The Parties agree that prior to submission of the Clinical Data for publication or presentation or any other dissemination of Clinical Data including oral dissemination, Shattuck shall provide to ImmunoGen full details and a full and final copy of the material to be published or presented according to the following procedure: at least thirty [***] prior to submission for publication of any manuscript, letter or any other publication, and at least [***] days prior to submission for presentation of any abstract, poster, talk or any other presentation. Upon written request from ImmunoGen, Shattuck agrees not to submit Clinical Data for publication/presentation for an additional thirty [***] in order to allow for actions to be taken to preserve rights for patent protection. Shattuck shall require that any other Publisher agree to publication obligations at least as stringent as those set forth herein.

11.1.2 ImmunoGen agrees not to submit any Clinical Data for publication or presentation or any other dissemination of Clinical Data including oral dissemination until Shattuck has published the Clinical Data, provided that ImmunoGen may publish in the circumstances where (i) Shattuck declines to publish within [***] after Study Completion or (ii) after publication of the Clinical Data by Shattuck, provided that in both cases ImmunoGen shall provide to Shattuck's Alliance Manager the full details of the content of the material and a full copy of the material to be published or presented according to the following procedure: at least [***] days prior to submission for publication of any manuscript, letter or any other publication, and at least [***] days prior to submission for presentation of any abstract, poster, talk or any other presentation. Upon written request from Shattuck, ImmunoGen agrees not to submit Clinical Data for publication/presentation for an additional [***] days in order to allow for actions to be taken which might be necessary to preserve rights for patent protection. ImmunoGen agrees not to include Confidential Information disclosed by Shattuck to ImmunoGen pursuant to this Agreement (except for Clinical Data) in any publication without the prior written consent of Shattuck and shall reasonably cooperate with Shattuck to resolve any issues related thereto.

11.1.3 The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in Section 11.1.1 to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication; *provided* that each Party, if the publishing Party, will accept and incorporate the other Party's reasonable comments to the extent such relate to such Party's Compound.

11.1.4 The publishing Party shall remove all Confidential Information (other than previously unpublished Clinical Data if the purpose of such publication or presentation is to disclose such data) of the other Party before finalizing the publication unless the other Party has affirmatively consented to such disclosure in writing.

11.2 *Press Releases*. Neither Party shall issue or permit the issuance of any press release or other public announcement relating to this Agreement or the Study without first obtaining the written consent of the other Party with respect to both the timing and content of such press release or other public announcement. Each Party agrees to identify the other Party and acknowledge the other Party's support in any press release and any other publication or presentation of the results of the Study.

12 Representations and Warranties; Disclaimers.

12.1 *Due Authorization*. Each of ImmunoGen and Shattuck represents and warrants to the other that: (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

12.2 *Compounds*.

12.2.1 *ImmunoGen Compound*. ImmunoGen hereby represents and warrants to Shattuck that (i) ImmunoGen has the full right, power and authority to grant all of the licenses granted to Shattuck under this Agreement and to carry out the provisions hereof, and (ii) ImmunoGen Controls the ImmunoGen Compound.

12.2.2 *Shattuck Compound*. Shattuck hereby represents and warrants to ImmunoGen that (i) Shattuck has the full right, power and authority to grant all of the licenses granted to ImmunoGen under this Agreement and to carry out the provisions hereof, and (ii) Shattuck *Controls* the Shattuck Compound.

12.3 *DISCLAIMER*. EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT, AND EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF TITLE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. NEITHER PARTY SHALL BE LIABLE FOR ANY USE THAT THE OTHER PARTY MAY MAKE OF THE CLINICAL DATA.

13 Insurance; Indemnification; Limitation of Liability.

13.1 *Insurance*. Each Party warrants that it maintains a policy or program of insurance at levels sufficient to support the indemnification obligations assumed herein with respect to claims of bodily injury or property damage. Upon request, each Party shall provide evidence of such insurance to the other Party.

13.2 *Indemnification*.

13.2.1 *Indemnification by Shattuck*. Shattuck agrees to defend, indemnify and hold harmless ImmunoGen, its Affiliates, and its and their employees, directors, subcontractors and agents (each an "**ImmunoGen Indemnified Party**") from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or the Study (a "**Third Party Claim**"); except to the extent that such Third Party Claim was caused by (i) the negligence or willful misconduct on the part of an ImmunoGen Indemnified Party; (ii) a breach on the part of ImmunoGen of any of its representations and warranties or any other covenants or obligations of ImmunoGen under this Agreement; (iii) a breach of Applicable Law by ImmunoGen; or (iv) a defect in the design, the manufacture, commercial packaging or labeling of the ImmunoGen Compound by ImmunoGen as well as a defect due to the handling of the ImmunoGen Compound by ImmunoGen before Delivery.

13.2.2 *Indemnification by ImmunoGen*. ImmunoGen agrees to defend, indemnify and hold harmless Shattuck, its Affiliates, and its and their employees, directors, subcontractors and agents (each a "**Shattuck Indemnified Party**") from and against any Third Party Claim to the extent such Third Party Claim arises from (i) the negligence or willful misconduct on the part of an ImmunoGen Indemnified Party in connection with this Agreement; (ii) Shattuck's use in the Study of any ImmunoGen Compound found to have a Non-Conformance (such use being prior to Shattuck becoming aware of such Non- Conformance); (iii) a breach on the part of ImmunoGen of any of its representations and warranties or any other covenants or obligations of ImmunoGen under this Agreement; (iv) a breach of Applicable Law by ImmunoGen; or (v) injuries and illness experienced by a Study subject resulting solely from administration of the ImmunoGen Compound; except to the extent that such Third Party Claim was caused by (a) the negligence or willful misconduct on the part of a Shattuck Indemnified Party; (b) a breach on the part of Shattuck of any of its representations and warranties or any other covenants or obligations of Shattuck under this Agreement; (c) a breach of Applicable Law by Shattuck; or (d) a defect due to the handling of the ImmunoGen Compound by Shattuck after Delivery.

13.2.3 *Procedure*. A Person seeking indemnification under Section 13.2 (the "**Indemnified Party**") in respect of a Third Party Claim shall give written notice within thirty (30) days of first knowledge of such Third Party Claim to the Party from which recovery is sought (the "**Indemnifying Party**"), provided that any failure to provide notice within such time period shall not relieve the Indemnifying Party of its obligations of indemnification with respect to such Third Party Claim unless and solely to the extent the Indemnifying Party is materially prejudiced by such delay, and shall permit the Indemnifying Party to assume direction and control of the defense of the Third Party Claim, provided that the Indemnifying Party shall act reasonably and in good faith with respect to the defense or settlement of such Third Party Claim as the defense or settlement relates to the Indemnified Party. The Indemnified Party, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation and defense of such Third Party Claim. The foregoing notwithstanding, the Indemnified Party shall have the right to participate in, but not control, the defense of any Third Party Claim, and request separate counsel, with such attorneys' fees and expenses or litigation to be paid by the Indemnified Party, unless (a)

representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential conflicting interests between such Indemnified Party and any other Person represented by such counsel in such proceedings, or (b) the Indemnifying Party has failed to assume the defense of the applicable Third Party Claim, and in connection with either clause (a) or (b) above, such reasonable attorneys' fees and expenses of litigation shall be paid by the Indemnifying Party. Neither the Indemnifying Party nor the Indemnified Party shall settle or otherwise resolve such Third Party Claim without the other's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed); provided that the Indemnifying Party may, without the Indemnified Party's prior written consent, agree or consent to any settlement or other resolution of such Third Party Claim which requires solely money damages paid by the Indemnifying Party, and which includes as an unconditional term thereof the giving by such claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such Third Party Claim.

13.2.4 *Insurance Proceeds*. Any indemnification payment hereunder shall be made net of any insurance proceeds which the Indemnified Party is entitled to recover; *provided*, however, that if, following the payment to the Indemnified Party of any amount under this Section 13.2, such Indemnified Party becomes entitled to recover any insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such indemnification payment) to the Indemnifying Party.

13.2.5 *Study Subjects*. Shattuck shall not offer compensation on behalf of ImmunoGen to any Study subject or bind ImmunoGen to any indemnification obligations in favor of any Study subject.

13.3 *LIMITATION OF LIABILITY*. IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (X) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (Y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATIONS IN CLAUSE (X) OR (Y) SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S FAILURE TO COMPLY WITH THE RESTRICTIONS UNDER THIS AGREEMENT WITH RESPECT TO CLINICAL DATA, CONFIDENTIAL INFORMATION, INVENTIONS AND SAMPLE TESTING RESULTS.

14 Use of Name.

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement without the other Party's prior written consent; *provided* that, consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of a Party so long as such use does not constitute an endorsement of any commercial product or service by the other Party.

15 Force Majeure.

Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of such Party, *provided* that financial inability in and of itself shall not be considered to be a force majeure event. In event of such force majeure, the Party affected thereby shall use [***] to cure or overcome the same and resume performance of its obligations hereunder.

16 Entire Agreement.

This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes any prior or contemporaneous agreements, understandings, negotiations or correspondence between the Parties, written or oral (*including*, without limitation, the Material Transfer and Evaluation Agreement) concerning the subject matter hereof. As of the Effective Date of this Agreement, the Material Transfer and

Evaluation Agreement is hereby terminated by the mutual agreement of the Parties and in the event of any conflict between this Agreement and the Material Transfer and Evaluation Agreement, this Agreement shall govern.

17 Amendment and Waiver.

This Agreement may be amended, modified or changed only by a written instrument executed by both Parties. No term of this Agreement will be deemed to have been waived and no breach excused, unless such waiver or consent shall be in writing and signed by the Party claiming to have waived or consented.

Any consent by any Party to, or waiver of, a breach by the other, whether express or implied, shall not constitute consent to, or waiver of, or excuse for, any other different or subsequent breach.

18 Binding Effect.

This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Except as set forth in Section 13.2 hereof, no Third Party (including, without limitation, employees of either Party) shall have or acquire any rights by reason of this Agreement.

19 Purpose and Scope.

The Parties hereto understand and agree that this Agreement is limited to the activities, rights and obligations as expressly set forth herein. Nothing in this Agreement shall be construed to establish any agency, employment, partnership, joint venture, franchise or similar or special relationship between the Parties. Neither Party shall have the right or authority to assume or create any obligations or to make any representations, warranties or commitments on behalf of the other Party, whether express or implied, or to bind the other Party in any respect whatsoever. Except as expressly set forth elsewhere in this Agreement, neither Party grants to the other Party any right or license to any of its intellectual property.

20 Headings.

Section and subsection headings are inserted for convenience of reference only and do not form part of this Agreement.

21 Assignment.

Neither Party may assign this Agreement without the prior written consent of the other Party, except that such consent shall not be required in connection with any assignment to an Affiliate of the assigning Party, or to a Third Party in connection with a sale or transfer of the business to which this Agreement relates, or to any successor Person resulting from any merger or consolidation of such Party with or into such Person, *provided* that the assignee shall have agreed in writing to assume all of the assignor's obligations hereunder, and *provided*, *further*, that the other Party shall be notified promptly after such assignment has been effected. Any such assignment shall not relieve the assigning Party of any liabilities or obligations owed to the other Party hereunder as of the date of assignment. Any purported assignment of this Agreement in violation of this Section 21 shall be null and void.

22 Notices.

All notices and communications shall be in writing and delivered personally or by courier or mailed via certified mail, return receipt requested, postage prepaid, addressed as follows:

If to ImmunoGen:

ImmunoGen, Inc. 830 Winter Street
Waltham, MA 02451-1477, USA
Attn: General Counsel
Email: [***]

If to Company:

Shattuck Labs, Inc.
500 W. 5th Street, Suite 1200
Austin, Texas 78701 Attn: General Counsel
Email: [***]

Except as otherwise expressly provided in this Agreement or mutually agreed in writing, any notice, communication or document (excluding payment) required to be given or made shall be deemed given or made and

effective upon actual receipt or, if earlier, (a) one (1) Business Day after deposit with a nationally recognized overnight express courier with charges prepaid, or (b) five (5) Business Days after mailed by certified mail, return receipt requested, postage prepaid, in each case addressed to the receiving Party at its address stated above or to such other address as such Party may designate by written notice given in accordance with this Section 22.

23 Severability.

If any provision of this Agreement shall be held by a court of competent jurisdiction, or declared under any law, rule or regulation of any government having jurisdiction over the Parties hereto, to be illegal, invalid or unenforceable, then such provision will, to the extent permitted by the court or government, not be voided, but will instead be construed to give effect to the intentions of the Parties to the maximum extent permissible under applicable law, and the remainder of this Agreement will remain in full force and effect in accordance with its terms.

24 Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

25 Dispute Resolution.

The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the Term relating to the conduct of the Study, either Party's rights or obligations hereunder or otherwise relating to the validity, enforceability or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Patent Rights (hereinafter, a **"Dispute"**). In the event of the occurrence of any such Dispute, the Parties shall, by written notice to the other Party, have such Dispute referred to their respective senior officers designated below, for attempted resolution by good faith negotiations commencing promptly after such notice is received. Said designated senior officials of the Parties are as follows:

For Company: Chief Executive Officer; and For ImmunoGen: Chief Executive Officer.

If the designated senior officials are not able to resolve such Dispute within [***] days following delivery of the notice referring the Dispute to the Parties' respective senior officers designated above, then such Dispute shall be finally resolved by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association by three arbitrators, of whom each Party shall designate one, with the third arbitrator to be designated by the two Party-designated arbitrators. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., and judgment upon the award rendered by the arbitrators may be entered by any court having competent jurisdiction thereof. The place of arbitration shall be the Borough of Manhattan, City of New York, New York.

26 Patent Disputes.

26.1 Inventorship. Any dispute, controversy or claim between the Parties involving the inventorship of any inventions conceived or first actually reduced to practice in connection with the conduct of the Study that is not resolved by mutual agreement of the Parties' respective chief patent counsels (or persons with similar responsibilities) within [***] days after the dispute is raised by one or both of the Parties shall be submitted to an Independent Patent Counsel for resolution. Such Independent Patent Counsel's determination of inventorship, absent manifest error, shall be final and binding on the Parties; *provided*, *however*, that any such determination with respect to any inventions described or claimed in a patent application shall not preclude either Party from disputing inventorship with respect to any different or additional inventions described or claimed in any patent issuing from such patent application, which disputes shall be resolved in accordance with this Section 26.1. The Parties shall equally (50/50) share the Independent Patent Counsel fees and expenses related to his or her determination of inventorship.

26.2 Other Patent Disputes. Any dispute, controversy or claim between the Parties that involves the validity, scope, infringement, enforceability or ownership of the Parties' respective Patent Rights (i) that are pending or issued in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction where the Party whose Patent Rights are the subject of such dispute, controversy or claim resides (*provided* that if such Party does not reside in the United States, venue shall be in the jurisdiction where such Party's principal U.S. Affiliate resides), and (ii) that are pending or issued in any other country (or region) shall be brought before an appropriate regulatory or administrative body or court in that country (or region), and the Parties hereby consent to the jurisdiction and venue of such courts and bodies.

27 Equitable Relief.

Anything contained in this Agreement to the contrary notwithstanding, if a Party reasonably requires equitable relief or relief on a more expedited basis than would be possible pursuant to the procedures set forth in Section 25 hereof, such Party may seek a temporary injunction or other equitable relief in a court of competent jurisdiction, without posting a bond. Any such remedies will be in addition to all other remedies available by law or at equity to the injured Party.

28 Execution.

This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each Party and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. If any signature is delivered by e-mail delivery of a "pdf" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such "pdf" signature page were an original thereof.

29 Interpretation.

The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to each Party hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement. In addition, unless the context otherwise requires, wherever used in this Agreement: (i) the singular shall include the plural, the plural the singular; (ii) the use of any gender shall be applicable to all genders; (iii) the word "or" is used in the inclusive sense (and/or); (iv) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation" (irrespective of whether such words are used in the applicable instance); (v) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not to any particular provision of this Agreement; and (vi) all references to "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

ImmunoGen, Inc.

By: /s/ Eric Westin
Eric Westin

Name
VP, Clinical Development & Translational Sciences

Title

Shattuck Labs, Inc.

By: /s/ Taylor Schreiber, MD, PhD
Taylor Schreiber, MD, PhD

Name
Chief Executive Officer

Title

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-263552, 333-254340, and 333-249555) on Form S-8 and the registration statement (No. 333-263553) on Form S-3 of our report dated February 23, 2023, with respect to the financial statements of Shattuck Labs, Inc.

/s/ KPMG LLP

Austin, Texas
February 23, 2023

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 15 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: February 23, 2023

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 15 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: February 23, 2023

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, 2022 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: February 23, 2023

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

Date: February 23, 2023

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.