# 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, 2023**

**OR**

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

**For the transition period from to**
**Commission File Number: 001-39593**

# Shattuck Labs, Inc.

**(Exact name of registrant as specified in its charter)**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §241.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023, was approximately $85,554,422 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 12, 2024, the registrant had 47,474,783 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 2024, 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," "develop", or the negative of these terms, and similar expressions intended to identify forward-looking statements. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. 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® product candidate 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. Our ARC® platform was designed to simultaneously inhibit checkpoint molecules and activate costimulatory molecules with a single therapeutic as a potential treatment for cancer. We also have at varying stages of preclinical development, dual-sided fusion proteins, distinct from our Agonist Redirected Checkpoint ("ARC") platform, that have therapeutic potential in autoimmune and inflammatory diseases, among other therapeutic areas.

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 1B clinical trial for the treatment of patients with ovarian cancer. We are also evaluating SL-172154 in an ongoing Phase 1B clinical trial for the treatment of patients with certain hematologic malignancies, including acute myeloid leukemia ("AML"), and higher-risk myelodysplastic syndromes ("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 demonstrate 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. Further, clinical data generated with our ARC platform has guided our preclinical research efforts to further expand our pipeline, and we are advancing certain potential product candidates through preclinical development. We expect to nominate one or more additional product candidates to our clinical pipeline in the future, potentially for indications outside of oncology, by selecting product candidates where there is an expectation of monotherapy efficacy and where our scientific and protein engineering expertise has led to a product candidate with advantages over current treatment modalities.

In February 2024, we announced a strategic collaboration and license agreement (the "Ono Agreement") with Ono Pharmaceutical Co., Ltd. ("Ono") in which we will lead research and preclinical development of certain compounds selected by Ono from our pipeline of bifunctional fusion proteins to a pair of prespecified targets for potential treatment of autoimmune and inflammatory diseases.

#### 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 1A/B clinical trial in patients with AML and HR-MDS. We completed the Phase 1A dose-escalation portion of this clinical trial in 2023 and are currently enrolling patients in the Phase 1B expansion cohorts evaluating SL-172154 in combination with azacitidine in frontline HR-MDS or frontline TP53 mutant ("TP53m") AML. In AML patients without TP53 mutations ("TP53 wild type", or "TP53wt"), we intend to study SL-172154 in combination with azacitidine and venetoclax. In December 2023, we shared initial data from both the HR-MDS and TP53m AML Phase 1B combination cohorts. In the frontline HR-MDS cohort, as of the data cutoff date of December 1, 2023, out of 14 evaluable patients, five patients achieved a complete response ("CR") and four patients achieved a marrow complete response ("mCR"). In the frontline TP53m AML cohort, as of the data cutoff date of December 1, 2023, out of 11 evaluable patients, two patients achieved a CR, and another patient achieved a complete response with incomplete hematologic recovery ("CRi") and was taken to allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). As of the cutoff date of December 1, 2023, SL-172154 had an acceptable safety and tolerability profile at 3 mg/kg in combination with azacitidine. After completing enrollment in the initial Phase 1B combination expansion cohorts in HR-MDS or TP53m AML patients in 2023, and on the basis of the encouraging

initial data, we are further expanding both cohorts to generate additional data and to inform our subsequent clinical trial plans. We expect to announce additional data from the HR-MDS and TP53m AML Phase 1B combination cohorts mid-year 2024.

We are also conducting a Phase 1B clinical trial evaluating SL-172154 in patients with platinum-resistant ovarian cancer ("PROC"). This Phase 1B clinical trial contains two combination expansion cohorts combining SL-172154 with either pegylated liposomal doxorubicin ("PLD"), or mirvetuximab soravtansine ("mirvetuximab" or, "Elahere").

In November 2023, we announced initial data from our ongoing Phase 1B clinical trial expansion cohort evaluating SL-172154 in combination with PLD. As of the data cutoff date of October 31, 2023, we had 11 patients evaluable for response, and we observed one confirmed partial response ("PR") and two unconfirmed PRs. As of the data cutoff of October 31, 2023, SL-172154 had an acceptable safety and tolerability profile at 3 mg/kg in combination with PLD.

We expect to announce additional data from the Phase 1B cohort in combination with PLD mid-year 2024 and initial data from the Phase 1B cohort in combination with mirvetuximab mid-year 2024.

The following table highlights our clinical-stage pipeline:

| | | Domains | | | | Stage of Development | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Platform | Program | Domain 1 | Domain 2 | Indications | Combination Agents | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 |
| ARC | SL-172154 | SIRPα | CD40L | PROC | Liposomal Doxorubicin | | | | | |
| | | | | PROC | Mirvetuximab Soravtansine | | | | | |
| | | | | TP53m AML | Azacitidine | | | | | |
| | | | | HR-MDS | Azacitidine | | | | | |
| | | | | TP53wt AML[1] | Azacitidine + Venetoclax | | | | | |

1. TP53wt AML cohort has not been initiated
PROC = Platinum-resistant ovarian cancer
AML = Acute myeloid leukemia
HR-MDS = Higher-risk myelodysplastic syndromes

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.

## 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 ("TNF") superfamily.

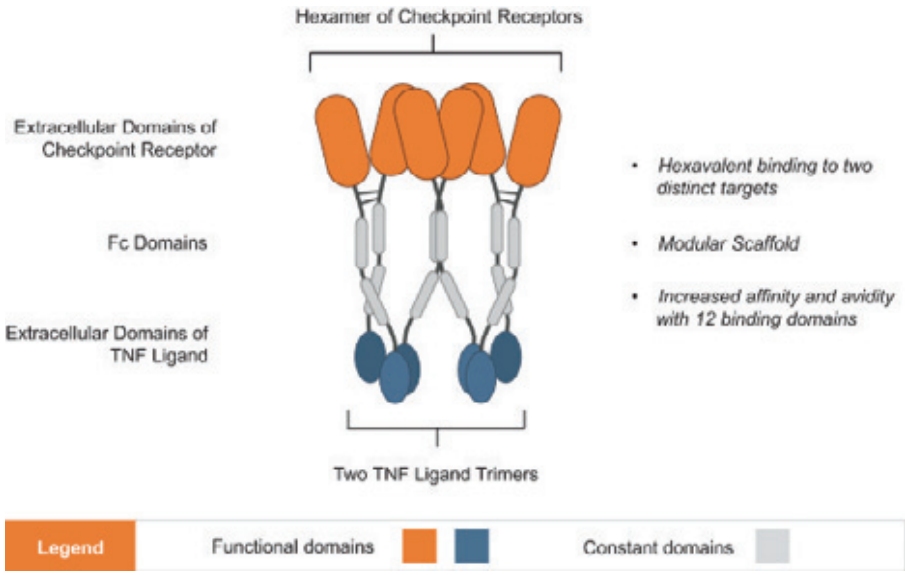
The functional domains of ARC compounds are derived from native human proteins, rather than antibody binding domains. This enables the rapid generation of new constructs, given that the starting template for distinct ARC compounds is the human genome. Therefore, an ARC compound can be taken from the 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

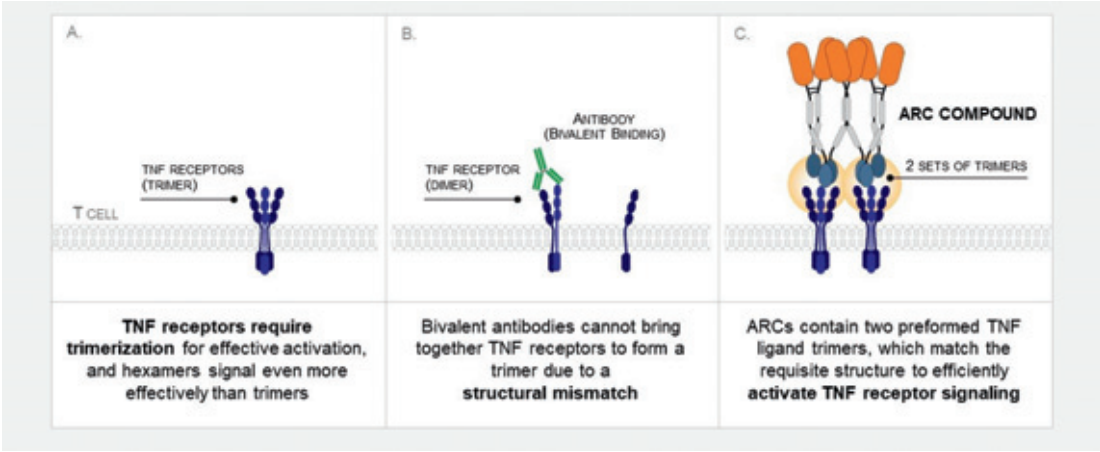
We believe these collective advantages create the potential for the capital-efficient identification and pursuit of differentiated product candidates.

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 (“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 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 platform and protein engineering expertise 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 platform to rapidly advance additional product candidates into clinical development
- Applying our clinical learnings from our ARC platform in oncology to identify, develop, and advance novel fusion protein compounds in autoimmune and inflammatory diseases, among other therapeutic areas
- 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***

*Overview*

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. 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, antibody-dependent cellular phagocytosis ("ADCP")-competent antibodies, antibody drug conjugates, and others.

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. We believe that our preclinical and initial clinical data from both our Phase 1A and Phase 1B clinical trials in PROC and Phase 1A/B clinical trial in HR-MDS and AML indicate that SL-172154 may differentiate from other CD47/SIRPα inhibitors in one or more of the following ways:

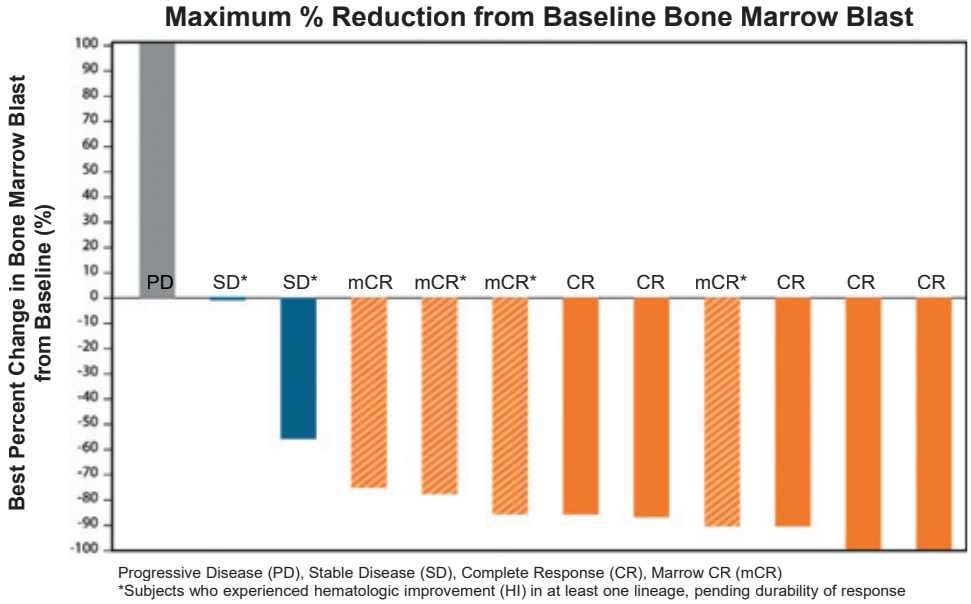
- Improved overall response rate due to CD40-mediated activation of both innate and adaptive immunity
- Improved response durability due to enhanced CD40-mediated activation of adaptive immunity
- Differentiated safety profile due to the absence of dose-limiting toxicities due to anemia or thrombocytopenia

*Acute Myeloid Leukemia and Higher-Risk Myelodysplastic Syndromes*

*Clinical Data to Date*

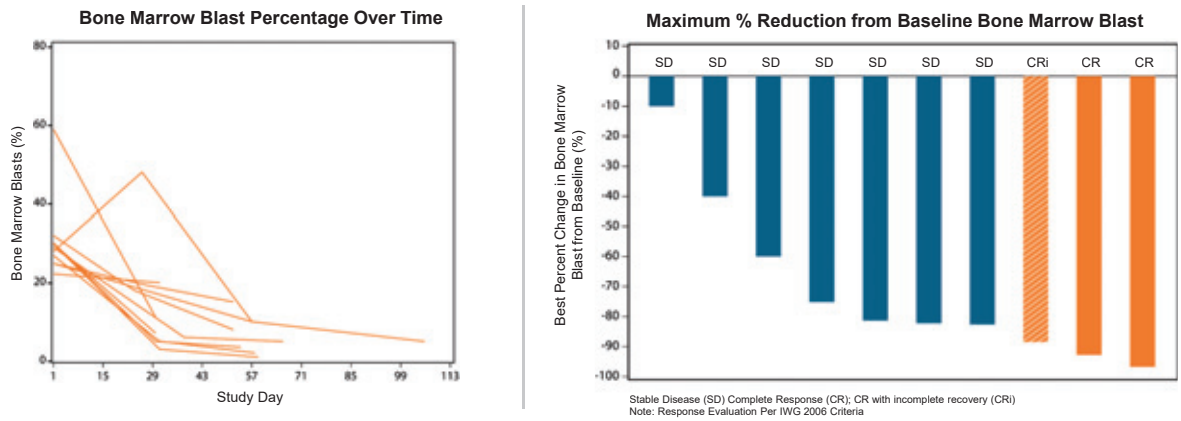
In December 2023, we announced initial data from the Phase 1B portion of our ongoing Phase 1A/B clinical trial evaluating SL-172154 in combination with azacitidine in frontline HR-MDS and TP53m AML. As of the data cutoff date of December 1, 2023, we had enrolled 22 patients with previously untreated HR-MDS. 14 of these patients were evaluable for response (13 of whom had TP53m or deletion), of which five patients achieved a CR, four patients achieved a mCR (three with hematologic improvement in at least one lineage), and two patients achieved stable disease ("SD") (both with hematologic improvement in at least one lineage). Figure 3 below depicts both the interim maximum percent reductions in bone marrow blasts from baseline and the interim best response in individual patients with HR-MDS as of December 1, 2023.

**Figure 3 — Interim Response Assessment & Percent Reductions in Bone Marrow Blasts in HR-MDS Patients**




As of the data cutoff date of December 1, 2023, we had enrolled 14 patients with previously untreated TP53m AML. 11 of these patients were evaluable for response, and two patients had achieved a CR and another patient achieved a CRi and was taken to allo-HSCT. Seven additional patients with stable disease had blast reductions, five of which had recovery of platelets or neutrophils and remain on study and their response may improve. Blast count reductions were observed in 100% of these patients. One patient died during the first cycle. The left panel of Figure 4 below, depicts the kinetics of bone marrow blast reductions from baseline in individual patients with TP53m AML as of December 1, 2023. The right panel of Figure 4 below depicts both the interim maximum percent reductions in bone marrow blasts from baseline and the interim best response in individual patients with TP53m AML as of December 1, 2023.

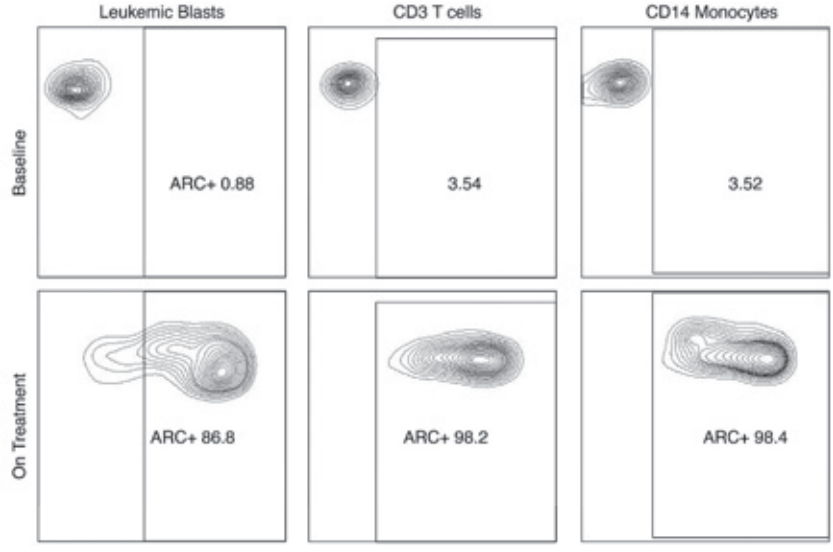
**Figure 4 — Kinetics of Bone Marrow Blast Reduction and Interim Response Assessment in TP53 Mutant AML Patients**




As of the data cutoff date of December 1, 2023, SL-172154 had an acceptable safety and tolerability profile. Infusion-related reactions ("IRRs") were the most common SL-172154 related treatment-emergent adverse events ("TEAEs"). In the HR-MDS and TP53m AML cohorts, IRRs were reported in seven patients (32%) and seven patients (50%) respectively. Grade 3 or 4 adverse events ("AEs") related to SL-172154 were reported in four patients (18%) in HR-MDS and two patients (14%) in TP53m AML, including; IRR (2), aspartate aminotransferase ("AST") increased (1), alanine aminotransferase ("ALT") increased (1), fatigue (1), hypoxia (1), pneumonia (1), chondrocalcinosis (1), and febrile neutropenia (1). There were no reports of destructive anemia. In the TP53m AML expansion cohort, there was one Grade 5 AE of cardiac arrest reported in one patient with history of coronary artery disease, recent arrhythmia, and hypokalemia in the setting of amiodarone use. In the HR-MDS cohort, there were no Grade 5 AEs related to SL-172154 reported.

Additionally, in December 2023, in a poster at the American Society for Hematology annual meeting, we announced data from the Phase 1A parallel staggered dose escalation trial of SL-172154 as monotherapy and in combination with azacitidine in primarily relapsed/refractory ("R/R") AML and HR-MDS patients. As of the data cut-off date of September 15, 2023, 32 adult patients with R/R AML or HR-MDS received SL-172154 as monotherapy or in combination with azacitidine in the parallel staggered dose-escalation portion of a Phase 1A/B clinical trial. Patients had a median of two prior lines of therapy. An additional five subjects with frontline TP53m HR-MDS received SL-172154 with azacitidine. We observed a monotherapy response in a heavily pre-treated R/R AML patient. This patient achieved a morphologic leukemia-free state and subsequently proceeded to allo-HSCT. Anti-tumor activity was also observed in combination with azacitidine in previously untreated TP53m HR-MDS patients. Out of four evaluable previously untreated TP53m HR-MDS patients, there was one CR and one mCR. Two patients, one with mCR and one with SD, proceeded to allo-HSCT. Additionally, we observed SL-172154 bound to both healthy immune cells and myeloid blast cells in bone marrow biopsies collected after intravenous infusion of SL-172154, as shown in Figure 5 below.

**Figure 5 — SL-172154 Binding to Leukemic Blasts, T Cells and Monocytes in Patient Bone Marrow Biopsies**



*Clinical Development Strategy and Upcoming Milestones*

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 with azacitidine. We completed the Phase 1A dose-escalation portion of this trial and subsequently completed enrollment in the initial Phase 1B expansion cohorts in combination with azacitidine in TP53m AML and HR-MDS patients during 2023. The Phase 1A dose-escalation portion of our clinical trial was primarily conducted in patients with R/R AML or HR-MDS, included both monotherapy SL-172154 cohorts and SL-172154 plus azacitidine combination cohorts, and supported selection of 3 mg/kg as the appropriate dose to explore in the Phase 1B expansion cohorts. The initial Phase 1B expansion cohorts were conducted in patients with previously untreated TP53m AML or HR-MDS, using the 3 mg/kg dose of SL-172154 in combination with azacitidine. Based on the initial safety and efficacy profile, we amended the protocol for both the TP53m AML and HR-MDS cohorts to add additional patients to strengthen our confidence in the safety and efficacy profile and to further inform our future clinical trial plans.

In TP53wt AML, we plan to evaluate SL-172154 in combination with both azacitidine and venetoclax. Azacitidine plus venetoclax is the standard of care for frontline TP53wt AML patients. We believe there may be an opportunity for the addition of SL-172154 to azacitidine plus venetoclax to differentiate from the current standard of care.

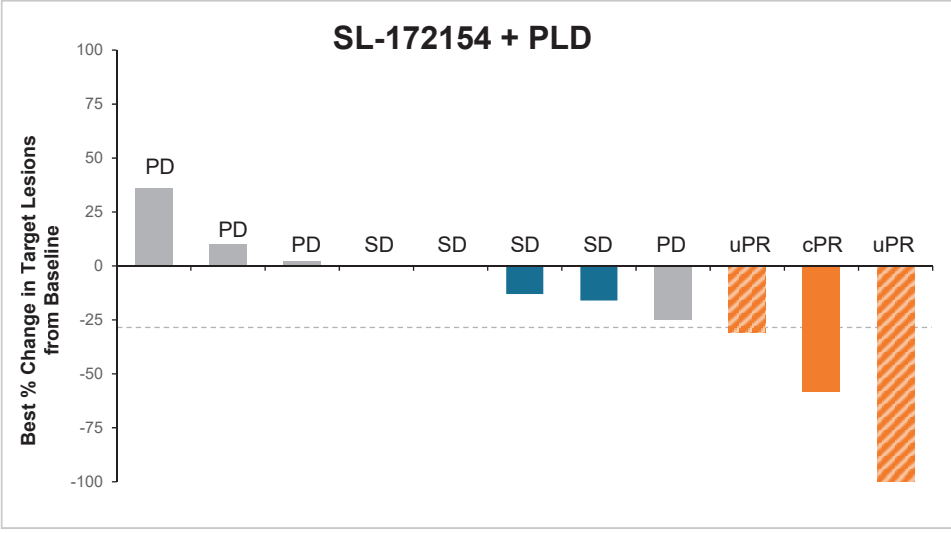
We expect to announce additional data from the Phase 1B expansion cohorts in previously untreated TP53m AML and HR-MDS, including safety, objective response rates and initial response durability mid-year in 2024.

*Platinum-Resistant Ovarian Cancer*

*Clinical Data to Date*

In November 2023, we announced initial data from our ongoing Phase 1B combination clinical trial evaluating SL-172154 in combination with PLD in PROC. As of the data cutoff date of October 31, 2023, we had enrolled 16 patients with PROC. 11 of these patients were evaluable for efficacy, and we observed one confirmed PR and two unconfirmed PRs. Patients had a median of 1.5 prior lines of systemic therapy, 88% were resistant to treatment with frontline platinum, 47% had bulky disease measuring >5 cm, and 56% were pre-treated with bevacizumab. As of the cutoff date, the patient population treated was similar to the population enrolled in the Pfizer-sponsored JAVELIN Ovarian 200 clinical trial (results published in 2021), wherein PLD monotherapy provided an overall response rate of 4%. Another clinical trial, the Roche-sponsored Aurelia trial (subgroup analysis published in 2014), provided for a 7.8% overall response rate for PLD monotherapy. Figure 6 below depicts the interim best percent change in the size of the target lesion, as well as interim best response, in individual patients with PROC, as of October 31, 2023.

**Figure 6 — Interim Response Assessment and Percent Change in Tumor Diameter in PROC Patients Treated with SL-172154 in Combination with PLD**




As of the cutoff date of October 31, 2023, SL-172154 in combination with PLD had an acceptable safety profile and is consistent with the safety profile of the individual agents. Among the 16 treated patients, the most common SL-172154-related AEs were IRRs, nausea, fatigue, headache and neutropenia, mostly in Grades 1 or 2. SL-172154-related AEs in Grades 3 or 4 were observed in six patients: anemia (n=2), AST increased (n=2), neutropenia (n=2), ALT increased (n=1), embolism (n=1) and thrombocytopenia (n=1). SL-172154-related IRRs occurred in four patients but were manageable and did not prevent the completion of dosing or lead to discontinuation. There were no Grade 5 adverse events.

In June 2023, in a poster presented at the American Society of Clinical Oncology annual meeting, we announced data from our Phase 1A monotherapy dose escalation clinical trial in PROC As of the data cutoff of January 3, 2023, 27 patients with PROC had been enrolled, with ovarian (70%), fallopian tube (15%) or primary peritoneal (15%) cancer. These patients had a median of four prior systemic therapies (range two to nine). As of a data cutoff date of January 3, 2023, 10 mg/kg was defined as the maximum administered dose, and a maximum tolerated dose was not reached.

As of the data cutoff of January 3, 2023, SL-172154 as monotherapy had an acceptable safety and tolerability profile. 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 were manageable by slowing the rate of infusion and/or by the administration of certain premedication(s). Grade 3/4 treatment-related AEs in greater than one patient were AST increased (G3) and lymphopenia (G4), each in 2 patients (7%); all were fully resolved with no dose modifications. There were no fatal AEs, no AEs that led to drug discontinuation and no events of cytokine release syndrome. The frequency of IRR events increased with increasing dose, and slowing the rate of infusion was utilized for mitigation. Importantly, however, we have not observed dose-limiting toxicities due to 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.

*Clinical Development Strategy and Upcoming Milestones*

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 completed the Phase 1A monotherapy dose-escalation clinical trial in patients with PROC in 2023. In this clinical trial, we reached a maximum administered dose of 10 mg/kg. We did not reach a maximum tolerated dose. Also in 2023, we completed initial enrollment to the Phase 1B dose-expansion portion of our clinical trial in PROC evaluating SL-172154 in combination with PLD. 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. PLD is a standard-of-care chemotherapy for this patient population. According to the literature, PLD upregulates calreticulin, an endogenous “eat me” signal, on the surface of tumor cells. Consequently, we believe that PLD 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 PLD and SL-172154 compared to PLD alone or SL-172154 alone. Furthermore, because the overall response rate of this patient population to PLD is approximately 4-8%, 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 PLD, we are evaluating SL-172154 in a Phase 1B combination dose-escalation and dose-expansion clinical trial in PROC in combination with mirvetuximab soravtansine, marketed by AbbVie, Inc (“AbbVie”) as Elahere. Mirvetuximab soravtansine is an antibody-drug conjugate (“ADC”) targeting folate receptor alpha (“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 PROC 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 data for both the PLD and mirvetuximab soravtansine combination trials in 2024. We expect to announce data, including topline overall response rate and an initial look at duration of response, from the Phase 1B combination clinical trial with PLD mid-year 2024. We also expect to announce initial data from the Phase 1B combination clinical trial with mirvetuximab soravtansine mid-year 2024.

*SL-172154 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.

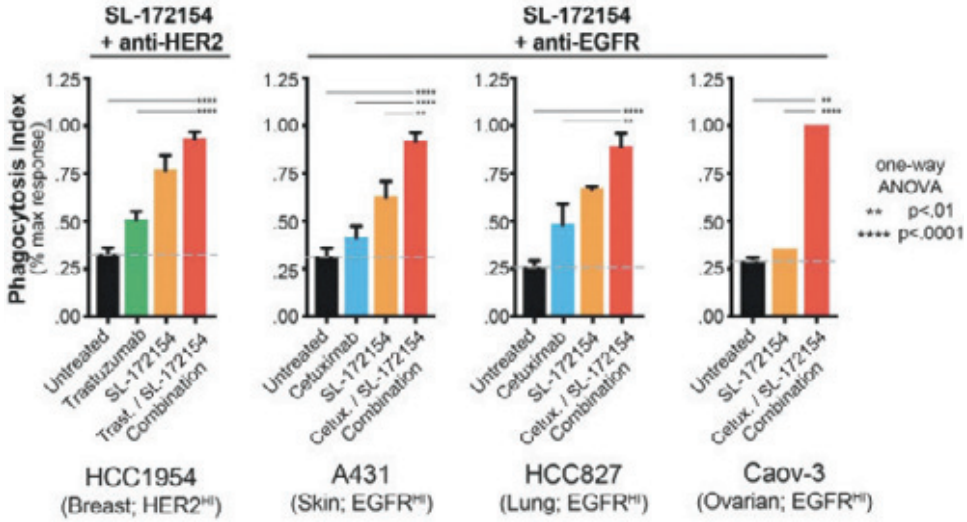
To date, we have conducted extensive preclinical studies of SL-172154 that have demonstrated the following:

- 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**

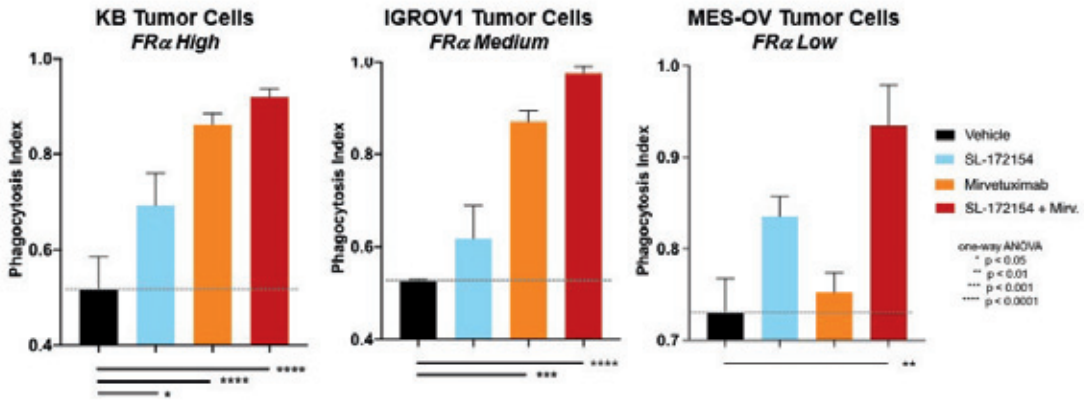



*Human monocyte derived macrophages were co-cultured with HCC1954, A431, HCC827, or Caov-3 cells in the presence of an IgG negative control, SL-172154, an ADCP-competent tumor-targeted antibody, including Trastuzumab or Cetuximab, or the combination of SL-172154 and the ADCP-competent tumor-targeted 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 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.*

*Preclinical Research and Development*

Our facility in Durham, North Carolina, houses our research laboratory as well as our technical operations group. This includes both expertise and infrastructure to advance novel biologics from discovery to cell line development, analytical and process development, and into production in our manufacturing pilot plant facility. These internal capabilities have enabled development of additional potential product candidates from our ARC platform in oncology indications. Further, these capabilities have led to collaborations with outside institutions, such as our studies to understand mechanisms of acquired resistance to checkpoint inhibitors with Memorial Sloan Kettering Cancer Center, Cancer Research UK, and Astra Zeneca, which were published in *Cancer Cell* in January 2024. In addition, we have produced and studied multiple dual-sided fusion proteins for non-oncology indications, including dual-sided TNFR2-Fc, CTLA4-Fc and GLP1-Fc fusion proteins. Another collaboration with Moderna was published in *Cancer Research* in February 2024, wherein the feasibility of delivering certain dual-sided fusion proteins as lipid-encapsulated mRNA was studied. This work has informed our internal plans for advancing certain dual-sided fusion proteins in non-oncology indications, wherein mRNA/LNP based delivery methods may provide pharmacokinetic, pharmacodynamic and pharmacoeconomic advantages in comparison to traditional, intravenous delivery of recombinant proteins for chronic, non-lethal diseases. Finally, the ARC platform was generated based on the goal of linking an immune checkpoint inhibitor to a TNF superfamily ligand. This expertise in TNF ligand and receptor biology has provided a basis to develop other potential product candidates to inhibit certain TNF receptors, including TNFRSF25.

**Collaboration and License Agreements**

***Strategic Collaboration and Option Agreement with Ono Pharmaceutical Co., Ltd.***

On February 9, 2024, we entered into the Ono Agreement, effective February 13, 2024, pursuant to which we and Ono will collaborate in the research and preclinical development of certain prespecified compounds directed toward a pair of targets selected by Ono from our pipeline of bifunctional fusion proteins (the "Development Compounds"). We are primarily responsible for carrying out the research activities in accordance with a mutually agreed upon research plan (the "Research Plan"), subject to the oversight of a joint research committee consisting of representatives from both parties. Pursuant to the Ono Agreement, we granted to Ono an exclusive option (the "Option") to obtain an exclusive, sublicensable license to research, develop, manufacture and commercialize multiple products resulting from the Development Compounds in any therapeutic area worldwide. The option period will extend from the effective date of the Ono Agreement until 90 days after we deliver our final report pursuant to the Research Plan, and following any exercise of the Option, Ono will be responsible for further development and commercialization of the Development Compounds.

In connection with entering into the Ono Agreement and conducting the Research Plan, we are entitled to receive up to $9 million consisting of an initial upfront payment and additional amounts payable upon the achievement of certain milestones specified in the Research Plan. Additionally, Ono has agreed to pay for all of our costs and expenses incurred in conducting the Research Plan.

In the event Ono exercises the Option for the Development Compounds, we are entitled to receive licensing, clinical and regulatory, and commercial milestone payments of up to $217.5 million upon the exercise of the Option, the achievement of certain specified clinical and regulatory milestones and commercial milestones and, in addition, a tiered percentage royalty on global net sales ranging from mid-single digits to low double digits. Royalties are payable by Ono on a licensed product-by-licensed product and country-by-country basis for a maximum of ten years after the first commercial sale of such licensed product in such country.

The Ono Agreement may be terminated by mutual agreement of both parties or by either us or Ono upon an uncured material breach of the Ono Agreement or the insolvency of the other party. Ono may terminate the Ono Agreement at any time upon 90 days' written notice to us. If Ono exercises such termination right, Ono will pay all of our costs up through the date of termination. In addition, after the conditions to exercise the Option have been met, we may terminate the Ono Agreement if Ono discontinues its development or commercialization efforts and other conditions are met.

The foregoing description of the Ono Agreement does not purport to be complete and is qualified in its entirety by reference to the Ono Agreement. We intend to file the Ono Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024.

***Clinical Trial Collaboration and Supply Agreement with ImmunoGen***

On February 4, 2022, we entered into a Clinical Trial Collaboration and Supply Agreement ("the Clinical Trial Collaboration Agreement"), with ImmunoGen, Inc. ("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 PROC,(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 (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.

In February 2024, ImmunoGen was acquired by AbbVie.

***Kopfkino License Agreement***

We are party to an Exclusive License Agreement (as amended, "the Kopfkino License Agreement"), with Kopfkino IP, LLC ("Kopfkino"). Pursuant to the Kopfkino License Agreement, we have (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 (the "Fusion Protein Patent Rights") and (2) a worldwide, sublicensable nonexclusive license to research, develop, manufacture, and commercialize certain know-how related to the Fusion Protein Patent Rights. We originally entered into the Kopfkino License Agreement in June 2016 with Scorpius Holdings, Inc. ("Scorpius") (f/k/a Nighthawk Biosciences, Inc. f/k/a Heat Biologics Inc.). The Kopfkino License Agreement was subsequently amended in November 2016, December 2016, and March 2017. In January 2024, Scorpius assigned its right, title and interest in and under the Kopfkino License Agreement, along with the underlying patents and patent applications, to Kopfkino.

Under the Kopfkino License Agreement, Scorpius was required to conduct certain research and development services under a mutually-agreed upon research and development plan and Scorpius was eligible to receive financial support from us for these efforts. Effective March 2017, Scorpius completed all research and development services under the Kopfkino 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 Kopfkino 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 ("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 Kopfkino on or before the anniversary of the effective date of the Kopfkino License Agreement to inform Kopfkino of our progress.

Unless sooner terminated or extended, the term of the Kopfkino 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 Kopfkino License Agreement due to a material breach by Kopfkino, Kopfkino must assign to us all right, title, and interest in the patent rights licensed under the Kopfkino License Agreement.

In addition to an upfront payment of $50,000, which we made in 2016, and a payment of $100,000 upon the successful completion of the first Phase 1 clinical trial, which we made in 2023, the Kopfkino License Agreement requires us to make further payments to Kopfkino in the future of up to $20.5 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 Kopfkino 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 Kopfkino 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 ("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 ("CHO") cells. SL-172154 has achieved cell culture titer greater than four 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 ("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 and our increased need for manufacturing driven by multiple clinical trial programs, we work to ensure that we have arrangements with multiple contract manufacturers to reduce the risk of single-source procurement of BDS. Additionally, in 2022, we completed the build out of 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. We believe that we have developed a manufacturing process for SL-172154 suitable for Phase 3 clinical trials and for supply of commercial drug product. A cGMP batch has not yet been initiated or completed using this improved process, however we expect that tech transfer of the manufacturing process and validation of a series of analytical methods required for release of drug substance and drug product to support Phase 3 clinical trials will be completed over the course of 2024 and into 2025. 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. It is possible that the competitive landscape for CD47 inhibitors may change over the course of 2024 as the sponsors of these compounds are no longer providing guidance to potential approvals, including magrolimab, TTI-621 and TTI-622.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and manufacturing capacity and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain U.S. Federal Food and Drug Administration ("FDA") or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, if required, the level of biosimilar or generic competition, and the availability of reimbursement from government and other third-party payors.

**Intellectual Property**

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

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

to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

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

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

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

In the United States, the term of a patent that covers an FDA-approved drug or biologic may be eligible for Patent Term Extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 (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 U.S. PTO reviews and approves the application for any Patent Term Extension in consultation with the FDA. In the future, we may decide to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant biologics license application.

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 February 1, 2024, we own or exclusively license (i) more than 25 patents and more than 20 pending non-provisional patent applications in the United States and (ii) 20 patents and more than 150 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 ("PCT"). Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. PTO and other patent offices may be significantly revised before issuance, if granted at all.

***SL-172154 Product Candidate***

As of February 1, 2024, we own or exclusively license (i) 6 patents and 6 pending non-provisional patent applications in the United States and (ii) 11 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, 2039, and 2042, 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 February 1, 2024, we own or exclusively license (i) more than 20 patents and 15 pending non-provisional patent applications in the United States and (ii) 11 patents and more than 125 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, 2040, and 2042, 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.

***Trademark Protection***

As of February 1, 2024, we own a registered trademark for "ARC" with the U.S. PTO. We plan to register trademarks in connection with our biological products.

***Licensed Intellectual Property from Kopfkino IP, LLC***

We are party to the Kopfkino License Agreement, with Kopfkino. Under the Kopfkino License Agreement, we have 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 are obligated to pay Kopfkino fees upon receipt of certain sublicensing income, achievement of certain milestones, and royalties upon sales of commercial products. The Kopfkino license provides us rights in the patent family including PCT/US16/54598. As of February 1, 2024, that family includes (i) 11 patents and 1 pending non-provisional patent applications in the United States, and (ii) 11 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. We originally entered into the Kopfkino License Agreement in June 2016 with Scorpius. The agreement was subsequently amended in November 2016, December 2016, and March 2017. In January 2024, Scorpius assigned its right, title, and interest in and under the Kopfkino License Agreement, along with the underlying patents and patent applications, to Kopfkino.

**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 ("FDCA"), the Public Health Service Act ("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 ("GLP") regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with cGMPs;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;

- preparation of and submission to the FDA of a biologics license application ("BLA") after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

***Preclinical and Clinical Development***

Prior to beginning 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 a partial or full clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

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

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

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

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple

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

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

***BLA Submission and Review***

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

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

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

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

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse

approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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

***Expedited Development and Review Programs***

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

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 safety or effectiveness of 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. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, the FDA established a new regenerative medicine advanced therapy ("RMAT") designation as part of its implementation of the 21st Century Cures Act. The 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.

***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.

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

***Post-Approval Requirements***

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. 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 AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, 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 ("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, 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 ("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 ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

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

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

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. 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 ("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 ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common 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.

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 $27,000.

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 the Health Information Technology for Economic and Clinical Health Act of 2009 ("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. The requirements imposed by HIPAA and HITECH on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity and availability of all PHI created, received, maintained or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of such breaches of PHI to individuals and regulators.

Significant civil and criminal fines and other penalties may be imposed for violating HIPAA. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

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 California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA"), which went into effect on January 1, 2020, creates new data privacy obligations for covered companies and provides new privacy rights to California residents. The CCPA/CPRA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, rights to California residents in relation to their personal information. Health information falls under the CCPA/CPRA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked with a particular consumer or household—unless it is subject to HIPAA—and is included under a new category of personal information, "sensitive personal information," which is offered greater protection.

***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 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 IRA, 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 (“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 European Economic Area (“EEA”) that are not considered by the European Commission (“EC”) to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses (“SCCs”). With regard to the transfer of data from the EEA to the US, on July 10, 2023, the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework. On the bases of the new adequacy decision, personal data can flow from the EEA to US companies participating in the 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 Clinical Trials Regulation (EU) No. 536/2014 ("CTR"), European Medicines Agency ("EMA") disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. 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 personal data from the EEA to the United Kingdom ("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, unless renewed. 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 UK GDPR, as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the "DPA 2018") ("UK GDPR"), the DPA 2018, and related data protection laws in the UK). Separately to the fines that can be imposed by the GDPR, the UK regime has the ability to impose fines up to the greater of £17.5 million or 4% of global turnover.

Following the UK's withdrawal from the EU and the EEA, companies are subject to specific transfer rules under the UK regime; personal data may flow freely from the UK to the EEA, since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. These UK international transfer rules broadly mirror the GDPR rules. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the European Commission's standard contractual clauses for international data transfers ("Addendum") and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime. However, the transitional provisions, adopted with the IDTA and the Addendum, provide that contracts concluded on or before September 21, 2022 on the basis of any old SCCs continue to provide appropriate safeguards for the purpose of the UK regime until March 21, 2024, provided that the processing operations that are the subject matter of the contract remain unchanged and reliance on those clauses ensures that the transfer of personal data is subject to appropriate safeguards.

With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States (the "UK-US Data Bridge"), which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension to the EU-US Data Privacy Framework.

*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 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 ("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 ("CTIS"). 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 GCP and GLP standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on GCP and the ethical principles that have their origin in the Declaration of Helsinki.

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

*Drug Marketing Authorization*

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

*Centralized Authorization Procedure*

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

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation. The current draft envisages, e.g., a shortening of the periods of data exclusivity, however, there is currently neither a final version of this draft nor a date for its entry into force.

*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, 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 ("SmPC") addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, i.e. the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a 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. 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 an 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 ("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 Periodic Safety Update Reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase 4 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 (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for cGMP. These requirements include compliance with EU cGMP 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 cGMP, 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 cGMP.

*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.

*Regulation in the UK and Other Markets*

The UK formally left the EU on January 31, 2020. EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework agreed by the UK and EU on February 27, 2023. Amongst other things, the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. From January 1, 2025, medicines will need to be approved and licensed on a UK-wide basis by the UK's Medicine and Healthcare products Regulatory Agency ("MHRA"), with medicines using the same packaging and labelling across the UK. The EMA will have no role in approving or licensing new drugs for provision in Northern Ireland. The EU and the UK have agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of cGMP, inspections of manufacturing facilities for medicinal products and issued cGMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

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

*Drug Marketing Authorizations*

To be used or sold in the UK, a drug must have an effective marketing authorization obtained by a centralized application through EMA or a national application. National applications are governed by the Human Medicines Regulations (SI 2012/1916) ("HMRs"). Applications are made electronically through the MHRA Submissions Portal. The process from application to authorizations generally takes up to 210 days, excluding time taken to provide any additional information or data required by the MHRA.

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

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain marketing authorization. Conversion refers to the procedure by which, as of January 1, 2021, MAs granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland but not in Great Britain, whereas, prior EU authorizations have all been automatically converted into UK MAs effective in Great Britain only.

*Orphan Designation*

In the UK, since January 1, 2021, a system for incentivizing the development of orphan medicines was introduced. Overall, the requirements for orphan designation largely replicate the requirements in the EU and the benefit of market exclusivity has been retained. Products with an orphan designation in the EU can be considered for an orphan marketing authorization in Great Britain, but a UK-wide orphan marketing authorization can only be considered in the absence of an active EU orphan designation. The MHRA will review applications for orphan designation at the time of a marketing authorization, and will offer incentives, such as market exclusivity and full or partial refunds for marketing authorization fees to encourage the development of medicines in rare diseases.

*Pediatric Development*

In the UK, the MHRA has published guidance on the procedures for UK Paediatric Investigation Plans ("PIPs") which, where possible, mirror the submission format and requirements of the EU system. EU PIPs remain applicable for Northern Ireland and EU PIPs agreed by the EMA prior to January 1, 2021 have been adopted as UK PIPs.

*Sales and Marketing Regulation*

EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK after its exit from the EU, through the HMRs. However, organizations wishing to sell medicines online need to register with the MHRA. The requirements to display the common logo no longer apply to UK-based online sellers, except for those established in 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**

As of December 31, 2023, we employed 75 full-time employees at two locations in the United States, in Austin, TX and Durham, NC.

We may hire additional employees in 2024 and beyond with a focus on increasing expertise and bandwidth in preclinical and clinical research and development, in-house process development and manufacturing, and clinical operations to support potential later-stage clinical trials. We continue to evaluate business needs and opportunities, with a hiring philosophy that seeks to balance in-house expertise with outsourced services, and management of overall operating expense. Currently, we outsource clinical trial work to clinical research organizations and drug manufacturing to contract manufacturers.

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

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

**Research and Development**

Research and development expenses for the years ended December 31, 2023 and 2022 were $74.3 million and $82.9 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 (the "Exchange Act"), including our annual reports on Form 10-K, our quarterly reports on Form 10-Q and our current reports on Form 8-K, and amendments to those reports, are accessible through our website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the Securities and Exchange Commission (the "SEC"). These SEC reports can be accessed through the "Investors" section of our website.

## Item 1A. Risk Factors

*Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Annual Report on Form 10-K 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.
- 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.
- 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.
- Our compounds, including those from our ARC platform, 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 platform, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those 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.

**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, 2023 and 2022, we reported a net loss of $87.3 million and $101.9 million, respectively. As of December 31, 2023, we had an accumulated deficit of $306.3 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.

***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 2026. 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 (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 platform, 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 platform, 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 platform, 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 periods of growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical operations, business development, manufacturing, regulatory affairs, quality assurance, human resources, legal, accounting and finance, and, ultimately, sales and marketing. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical, and managerial employees. If our recruitment and retention efforts are unsuccessful, when needed, in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

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

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

***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.

**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 have publicly disclosed, and we may publicly disclose again in the future, 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 have reported or may report in the future 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. In addition, at times we have access to additional data, in part because our trials are open-label, beyond what has been publicly disclosed. 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 independent institutional review boards of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or are only moderately positive, or if there are safety concerns, our business and results of operations may be materially and adversely affected, and we may incur significant additional costs.

***Our 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 AEs.

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 (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. 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, the United Kingdom of Great Britain, 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. 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. In August 2022, President Biden signed into law 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."

In addition, the FDA or comparable foreign authorities may change the requirements for clinical development and approval, which may alter our clinical development plans and increase our costs. For example, the FDA published guidance in January 2023 on "Project Optimus," an initiative to improve dose selection in oncology drug development with the goal of optimizing the design of early dose-finding trials. If the FDA does not believe we have sufficiently demonstrated that the selected doses for our product candidates maximize not only the efficacy of such candidate, but the safety and tolerability as well, our ability to progress our clinical trials and ultimately commercialize a product candidate may be delayed and our costs may be increased.

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

***We may seek designations under FDA programs designed to facilitate and potentially expedite product candidate development, such as Fast Track or Breakthrough Therapy Designation. If we decide to pursue a Fast Track or Breakthrough Therapy Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.***

We may seek a Fast Track or Breakthrough Therapy Designation for a product candidate. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for one or both of these designations, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track or Breakthrough Therapy Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track or Breakthrough Therapy Designation if it believes that the designation is no longer supported by data from our clinical development program. See the section titled "Business—Government Regulation—Expedited Development and Review Programs" for a more detailed description of the process for seeking Fast Track and/or Breakthrough Therapy Designation.

***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 ("CROs"), consultants, commercial partners, suppliers, and vendors acting for us or on our behalf may engage in misconduct or other improper activities, including noncompliance with applicable laws and regulations.***

We have adopted a code of conduct, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

**Risks Related to 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 currently are pursuing 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 currently are pursuing the development of our product candidates in combination with other approved therapeutics, and we have commenced clinical trials of our product candidates in combination with other approved therapeutics in the future. We have not developed or obtained regulatory approval for, nor will we manufacture or sell, any of these approved therapeutics. In addition, the combinations have 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 AEs 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 will not be able to continue clinical development of or market any product candidate in combination with such revoked therapeutic. If safety or efficacy issues 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 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. 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. We are preparing to scale up to a Phase 3 and commercial manufacturing process, including transferring our manufacturing process to contract development and manufacturing organizations ("CDMOs"), including those that may not yet have completed a cGMP campaign with our product. There is no guarantee that the CDMOs that have produced our clinical trial material to date will be suitable for Phase 3 or commercial manufacturing. Our product candidate has not yet been manufactured on a commercial scale, and there are risks associated with the scaling up of the manufacturing process including, CDMO selection, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, supply chain disruptions and timely availability of raw materials. Even if we obtain regulatory approval for SL-172154, there is no assurance that the manufacturer or manufacturers we have arranged will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand.

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 good clinical practice regulations, such data may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or nonclinical studies, or clinical trials before approving our marketing applications. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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, including our collaboration with Ono, 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. For example, if Ono decides not to exercise its option to obtain an exclusive, sublicensable license to research, develop, manufacture and commercialize products resulting from the Development Compounds under the Ono Agreement, we would not receive any of the potential licensing fees or clinical, regulatory and commercial milestone payments thereunder. 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 platform, 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. PTO, and foreign patent offices; lack of perfect visibility into what our competitors are doing and the patent claim scope they are obtaining; lack of perfect ability to determine what prior art may exist; and the expense and time consuming nature of patent portfolio development across relevant jurisdictions. For at least these reasons, the issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. We cannot be sure that patent coverage will issue, or will be maintained, to protect our products in some or all relevant jurisdictions. We cannot be sure that we will not encounter freedom-to-operate challenges in the development and commercialization of our product candidates. We cannot be sure our

trademarks and trade names are sufficient to build name recognition in our markets of interest. We cannot be sure our measures to protect our trade secrets will be sufficient. Failure to protect or enforce these rights adequately could harm our ability to develop and market our product candidates and could impair our business.

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

Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if patents do successfully issue and even if such patents cover our product candidates and extend for a commercially-relevant time, third parties may initiate invalidity, non-infringement, opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation actions in court, before patent offices, or similar proceedings challenging the validity, inventorship, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, held unenforceable, or circumvented. Such challenges and potential negative results could materially and adversely affect our business.

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

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

Others may accuse us of infringing their intellectual property. Contested proceedings are lengthy, time consuming, and costly, and we cannot guarantee that our operations and activities do not, or will not in the future, infringe existing or future patents. We also cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our product candidates or necessary for the commercialization of our product candidates in any jurisdiction. Furthermore, we may be subject to third-party claims asserting that our employees, consultants, contractors, collaborators, or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property. These and related risks to defending against third-party claims may materially and adversely affect our business.

Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. As such, there may be applications of third parties now pending or recently revived patents of which we are unaware.

Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. We cannot provide any assurances that third-party patents do not exist that might be enforced against our current technology, including our platform technologies, product candidates and their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture, future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our product candidates or other attributes of our product candidates, or our compounds, including those from our ARC platform. 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. The patent laws of the U.S. and foreign jurisdictions, as well as the rules of the U.S. PTO and foreign patent offices, change from time to time. Further changes to the patent laws and/or rules of the U.S. PTO and foreign patent offices may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. The Supreme Court and other federal courts also regularly rule on patent cases, including those involving the life sciences. Those decisions can change the interpretation of patent laws; for example, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. These changes to patent laws and subsequent court decisions related to patent rights have created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts and the U.S. PTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

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

- others may be able to make product candidates similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have a material and adverse effect on our business;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights;
- our pending patent applications might not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we cannot predict the degree and range of protection any issued patents will afford us against competitors, whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications, or whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

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

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

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

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

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

There could be public announcements of the results of or developments in hearings, motions or other interim proceedings and if securities analysts or investors perceive these results or developments to be negative, it could have a material and adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Infringement or related suits against us by others could result in damages awards against us or injunction or other equitable relief precluding continued commercialization of our products. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent

application process and in order to maintain the patent once issued. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents within prescribed time limits. If we fail to maintain the patents and patent applications covering our product candidates or if we otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would have a material and adverse effect on our business.

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

In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information in digital form. Despite the implementation of security measures, our information technology systems and data, and those of our current or future CROs or other contractors and consultants, are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Although, to our knowledge, we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations or subject us to litigation or regulatory actions taken by governmental authorities. See Part I, Item 1. "Business—Government Regulation—Data Privacy and Security" and Part I, item 1C. "Cybersecurity." Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price, stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

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

**Risks Related to Ownership of Our Common Stock**

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

The market price of our common stock may be highly volatile and may fluctuate significantly as a result of a variety of factors, some of which are related in complex ways and many of which are beyond our control, including the factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

In addition, the stock market in general, and The Nasdaq Stock Market, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. We have in the past been subject to securities class action litigation following periods of volatility in the market price of our securities. While this litigation was settled, if any similar litigation was instituted in the future, it could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. See the discussion of Legal Proceedings in Part I, Item 3 of this Form 10-K.

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

As of February 1, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position and may be able to determine all matters requiring stockholder approval.

For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

**General Risk Factors**

***Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.***

The global economy, including credit and financial markets, has experienced 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, higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending, and ongoing military conflicts throughout the world have 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.

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

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

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

The trading market for our common stock depends in part upon research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. 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 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. In addition, a change in our filer status could trigger a requirement to begin complying with Section 404(b) of the Sarbanes-Oxley Act of 2002, and our independent registered public accounting firm would have to evaluate and report on the effectiveness of internal control over financial reporting, increasing our costs. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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

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

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

***We may become exposed to costly and damaging liability claims, either when testing 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 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, 2023, we had U.S. federal and state net operating loss ("NOL"), carryforwards of $149.5 million, which may be available to offset future taxable income. As of December 31, 2023, we also had gross federal tax credits of $16.9 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 1C. Cybersecurity**

In the ordinary course of our business, we collect, use, store, and transmit digitally large amounts of confidential, sensitive, proprietary, personal, and health-related information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by dedicated information technology resources, including both company and consultant personnel, and led by our Chief Business Officer. The processes include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. For example, we conduct penetration and vulnerability testing, data recovery testing, security audits, and ongoing risk assessments of our IT environment.

We also conduct technology due diligence on and audits of our key vendors, CROs, and other contractors and suppliers supporting our clinical trials. We also conduct regular employee trainings on cyber and information security. In addition, we consult with experienced outside advisors and experts on a regular basis to assist with assessing, identifying, and managing cybersecurity risks.

Our Chief Business Officer, who reports directly to the Chief Executive Officer, together with certain members of our senior leadership team, are responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework evaluated at least quarterly. In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors," under the heading "Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could materially and adversely affect our business."

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

**Item 2. Properties**

Our corporate headquarters are located in Austin, Texas where we currently occupy approximately 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 our 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 cited the volatility in our common stock and alleged that the defendants made or were responsible for misleading omissions regarding the Company's clinical trial results and the collaboration agreement with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company, Ltd.. The court approved the parties settlement of the plaintiffs' claims in the amount of $1.4 million and entered a final judgment dismissing the class action claims with prejudice on November 6, 2023. The Company paid the amount to the escrow agent for the settlement on June 19, 2023.

We may in the future be involved in legal proceedings, claims, investigations and government inquires arising in the ordinary course of our business. 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**

Not applicable.

## 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 12, 2024, there were approximately 29 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 ("IPO") as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 13, 2020.

### Item 6. Reserved

Not applicable.

### 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. Our ARC® platform was designed to simultaneously inhibit checkpoint molecules and activate costimulatory molecules with a single therapeutic as a potential treatment for cancer. We also have at varying stages of preclinical development, dual-sided fusion proteins, distinct from our ARC platform, that have therapeutic potential in autoimmune and inflammatory diseases, among other therapeutic areas.

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 1B clinical trial for the treatment of patients with ovarian cancer. We are also evaluating SL-172154 in an ongoing Phase 1B clinical trial for the treatment of patients with certain hematologic malignancies, including AML and 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 demonstrate 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. Further, clinical data generated with our ARC platform has guided our preclinical research efforts to further expand our pipeline, and we are advancing certain potential product candidates through preclinical development. We expect to nominate one or more additional product candidates to our clinical pipeline in the future, potentially for indications outside of oncology, by selecting product candidates where there is an expectation of monotherapy efficacy and where our scientific and protein engineering expertise has led to a product candidate with advantages over current treatment modalities.

In February 2024, we entered into the Ono Agreement in which we will lead research and preclinical development of certain compounds selected by Ono from our pipeline of bifunctional fusion proteins to a pair of prespecified targets for potential treatment of autoimmune and inflammatory diseases.

***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 the sale of our common stock and pre-funded warrants for approximately $261.1 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 $84.2 million.

For the years ended December 31, 2023 and 2022, our net loss was $87.3 million and $101.9 million, respectively. We have not been profitable since inception, and as of December 31, 2023, we had an accumulated deficit of $306.3 million and $130.6 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;
- 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, including scale up of our Phase 3 and commercial manufacturing process;
- initiate nonclinical studies and clinical trials for additional product candidates that we may identify in the future;
- 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 one or more of our product candidates.

**Global Economic Considerations**

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, financial institution instability, instability in the geopolitical environment, and lingering effects of the COVID-19 pandemic. Such challenges have caused, and may continue to cause, recession fears, high interest rates, foreign exchange volatility and inflationary pressures. At this time, we are unable to quantify the potential effects of this economic instability on our future operations.

**Components of our Results of 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 and research agreements with various third parties,

Revenue recognized in 2023 was a result of a clinical trial collaboration agreement with ImmunoGen in which activities began in 2023 and will continue in 2024. We expect to recognize a total of $2 million of revenue under this collaboration agreement. In February 2024, ImmunoGen was acquired by AbbVie.

In February 2024, we entered into the Ono Agreement in which we will lead research and preclinical development of certain compounds selected from our pipeline of bifunctional fusion proteins directed to a pair of prespecified targets for potential treatment of autoimmune and inflammatory diseases. We are primarily responsible for carrying out the research activities in accordance with a mutually agreed upon research plan, which we expect to start in 2024. In connection with entry into the Ono Agreement, we are entitled to receive up to $9 million consisting of an initial upfront payment and additional payments upon the achievement of certain specified milestones in the Research Plan. Additionally, Ono has agreed to pay for all of our costs and expenses incurred in conducting the Research Plan. We expect to begin recognizing revenue associated with the conduct of the Research Plan in 2024.

In the event Ono exercises its Option to further development their specified Development Compounds, we are entitled to receive licensing and development, regulatory and commercial milestone payments of up to $217.5 million, in the aggregate, and a tiered royalty on sales upon commercialization.

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 clinical trials, including SL-172154 and any potential product candidates we may advance in the future;
- costs of manufacturing nonclinical study and clinical trial materials, including the costs of raw materials required for manufacturing;
- process development activities to optimize manufacturing processes, including the development and validation of Phase 3 and commercial manufacturing processes and analytical methods;
- expenses incurred to conduct our nonclinical studies, including research conducted on our wholly-owned compounds and those subject to the Ono Agreement;
- 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, 2023 | 2022 |
|---|---|---|
| SL-172154 | $ 30,653 | $ 38,609 |
| Other pipeline compounds | 16,261 | 17,373 |
| Internal costs, including personnel related benefits, facilities, and depreciation | 27,396 | 26,917 |
| | $ 74,310 | $ 82,899 |

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 2024, including expenses associated with the conduct of the Research Plan pursuant to the Ono Agreement. 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, which may include a material expansion of our existing clinical trials or the initiation of planned, later-stage clinical trials for our current and/or future product candidates, pursue regulatory approval of our product candidates, or advance additional product candidates from 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;
- 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 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 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, 2023 and 2022***

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022.

| (in thousands) | Year Ended December 31, 2023 | 2022 | Change Dollar | Percentage |
|---|---|---|---|---|
| Collaboration revenue | $ 1,657 | $ 652 | $ 1,005 | 154.1 % |
| Operating expenses: | | | | |
| Research and development | 74,310 | 82,899 | (8,589) | (10.4)% |
| General and administrative | 19,304 | 21,082 | (1,778) | (8.4)% |
| Loss from operations | (91,957) | (103,329) | 11,372 | (11.0)% |
| Other income | 4,659 | 1,384 | 3,275 | 236.6 % |
| Net loss | $ (87,298) | $ (101,945) | $ 14,647 | (14.4)% |

*Collaboration Revenue*

Collaboration revenue increased by $1.0 million, or 154.1%, to $1.7 million for the year ended December 31, 2023 from $0.7 million for the year ended December 31, 2022. The increase in collaboration revenue was primarily attributable to an increase in clinical activity associated with our clinical trial collaboration agreement with ImmunoGen. In the second quarter of 2022, we executed a collaboration agreement with another third party and 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 decreased by $8.6 million, or 10.4%, to $74.3 million for the year ended December 31, 2023 from $82.9 million for the year ended December 31, 2022. The decrease in research and development expense was primarily a result of a decrease in the cGMP manufacture of clinical trial material of $13.8 million and a decrease in materials consumed in our lab of $1.2 million, offset primarily by increases in costs associated with the conduct of clinical trials for SL-172154 of $4.2 million, depreciation of fixed assets of $1.0 million and facility costs of $0.8 million related to the expansion of our in-house manufacturing and development capabilities.

*General and Administrative Expense*

General and administrative expenses decreased by $1.8 million, or 8.4%, to $19.3 million for the year ended December 31, 2023 from $21.1 million for the year ended December 31, 2022. The decrease in general and administrative expenses was primarily a result of recognizing the litigation settlement of $1.4 million in 2022 and a $1.0 million decrease in company insurance costs, primarily related to directors and officers insurance, offset by an increase in stock-based compensation of $0.6 million.

**Liquidity and Capital Resources**

Since our inception, our primary sources of liquidity have been generated by sales of our common stock, pre-funded warrants, convertible preferred stock, convertible notes, and collaboration agreements. As of December 31, 2023, we had an accumulated deficit of $306.3 million and $130.6 million of cash and cash equivalents and investments.

On December 26, 2023, we sold 4,651,163 shares of common stock through an underwritten public offering, and concurrently completed a private placement of 3,100,823 pre-funded warrants for net proceeds of $47.6 million. The purchase price per share of common stock was $6.45, and the purchase price per pre-funded warrant was $6.4499 which was the purchase price per share of common stock, minus the $0.0001 per share exercise price of such pre-funded warrant. Each pre-funded warrant may be exercised for one share of common stock, is immediately exercisable, does not expire, and is subject to

a beneficial ownership limitation of 9.99% post-exercise. As of December 31, 2023, no pre-funded warrants have been exercised, and 3,100,823 pre-funded warrants remain outstanding.

In July 2022, we entered into a sales agreement (the "Sales Agreement"), with SVB Securities LLC (the "Sales Agent"), pursuant to which we may offer and sell up to $75.0 million of shares of our common stock from time to time (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 February 29, 2024 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 continuing to incur 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, 2023 are sufficient to fund projected operations into 2026.

***Cash Flows***

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

| (in thousands) | Year ended December 31, 2023 | 2022 |
|---|---|---|
| Net cash used in operating activities | $ (81,228) | $ (94,498) |
| Net cash provided by investing activities | 110,859 | 49,438 |
| Net cash provided by financing activities | 48,616 | 171 |
| Net increase (decrease) in cash and cash equivalents | $ 78,247 | $ (44,889) |

*Net Cash Used in Operating Activities*

During the year ended December 31, 2023, net cash used in operating activities was $81.2 million and primarily reflected our net loss of $87.3 million and $4.1 million net change in our operating assets and liabilities, and was offset by noncash charges of $6.9 million in stock-based compensation, $2.9 million in depreciation expense, amortization of investments and non-cash operating lease expense and $0.3 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, 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, and was 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.

*Net Cash Provided by Investing Activities*

During the year ended December 31, 2023, net cash provided by investing activities was $110.9 million due to a $111.3 million increase in cash due to maturities of investments net of purchases, offset by $0.4 million in fixed asset purchases.

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 $11.6 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.

*Net Cash Provided by Financing Activities*

During the year ended December 31, 2023, net cash provided by financing activities was $48.6 million and was from the sale of common stock and pre-funded warrants for net cash proceeds of $48.2 million and the exercise of stock options and purchases pursuant to our employee stock purchase plan of $0.5 million.

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.

**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 ("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, "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, 2023.

**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 $1.235 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 Exchange Act. We will continue to be a smaller reporting company so long as (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. 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, 2023 and December 31, 2022, the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended December 31, 2023, 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, 2023 and December 31, 2022, and the results of its operations and its cash flows for the years then ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

*Basis for Opinion*

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG

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

Austin, Texas
February 29, 2024

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

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 125,626 | $ 47,379 |
| Investments | 4,999 | 113,901 |
| Prepaid expenses and other current assets | 12,595 | 23,304 |
| Total current assets | 143,220 | 184,584 |
| Property and equipment, net | 13,804 | 17,671 |
| Other assets | 2,540 | 3,069 |
| Total assets | $ 159,564 | $ 205,324 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,587 | $ 7,170 |
| Accrued expenses and other current liabilities | 9,866 | 17,795 |
| Total current liabilities | 11,453 | 24,965 |
| Non-current operating lease liabilities | 3,406 | 4,202 |
| Total liabilities | 14,859 | 29,167 |
| Commitments and contingencies (Note 7) | | |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value: 300,000,000 shares authorized, 47,260,108 shares issued and outstanding at December 31, 2023 and 42,390,586 shares issued and outstanding at December 31, 2022 | 5 | 5 |
| Additional paid-in capital | 451,006 | 396,041 |
| Accumulated other comprehensive income (loss) | 4 | (877) |
| Accumulated deficit | (306,310) | (219,012) |
| Total stockholders' equity | 144,705 | 176,157 |
| Total liabilities and stockholders' equity | $ 159,564 | $ 205,324 |

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, | |
|---|---|---|
| | 2023 | 2022 |
| Collaboration revenue | $ 1,657 | $ 652 |
| Operating expenses: | | |
| Research and development | 74,310 | 82,899 |
| General and administrative | 19,304 | 21,082 |
| Expense from operations | 93,614 | 103,981 |
| Loss from operations | (91,957) | (103,329) |
| | | |
| Other income (expense): | | |
| Interest income | 4,669 | 1,592 |
| Other | (10) | (208) |
| Total other income | 4,659 | 1,384 |
| Net loss | $ (87,298) | $ (101,945) |
| Unrealized gain (loss) on investments | 881 | (317) |
| Comprehensive loss | $ (86,417) | $ (102,262) |
| | | |
| Net loss per share - basic and diluted | $ (2.05) | $ (2.41) |
| Weighted-average shares outstanding - basic and diluted | 42,600,190 | 42,378,895 |

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 Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| 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 |
| Proceeds from sale of common stock and pre-funded warrants, net of issuance cost | 4,651,163 | — | 47,580 | — | — | 47,580 |
| Stock-based compensation expense | — | — | 6,939 | — | — | 6,939 |
| Proceeds from exercise of stock options and purchase of common stock pursuant to employee stock purchase plan | 158,274 | — | 499 | — | — | 499 |
| Issuance of common stock upon settlement of restricted stock units | 77,312 | — | — | — | — | — |
| Taxes paid related to net share settlement of | (17,227) | — | (53) | — | — | (53) |
| Unrealized gain on investments | — | — | — | 881 | — | 881 |
| Net loss | — | — | — | — | (87,298) | (87,298) |
| Balance at December 31, 2023 | 47,260,108 | $ 5 | $ 451,006 | $ 4 | $ (306,310) | $ 144,705 |

See accompanying notes to financial statements

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

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Cash flows from operating activities: | | |
| Net loss | $ (87,298) | $ (101,945) |
| Adjustments to reconcile net loss to net cash used in operations: | | |
| Stock-based compensation | 6,939 | 6,462 |
| Depreciation | 4,042 | 3,073 |
| Amortization of (discount) premium on debt securities | (1,483) | 1,370 |
| Non-cash operating lease expense | 364 | 302 |
| Loss on sale of assets | 303 | 704 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 10,458 | (3,842) |
| Other assets | 165 | (53) |
| Accounts payable | (5,629) | (2,842) |
| Accrued expenses and other current liabilities | (8,636) | 2,975 |
| Non-current operating lease liabilities | (796) | (702) |
| Deferred revenue | 343 | — |
| Net cash used in operating activities | (81,228) | (94,498) |
| Cash flows from investing activities: | | |
| Sale and maturities of investments | 190,999 | 193,325 |
| Purchases of investments | (79,733) | (132,377) |
| Purchases of property and equipment | (407) | (11,614) |
| Sale of property and equipment | — | 104 |
| Net cash provided by investing activities | 110,859 | 49,438 |
| Cash flows from financing activities: | | |
| Proceeds from sale of common stock and pre-funded warrants, net of issuance cost | 48,170 | — |
| Proceeds from the exercise of stock options and purchases of common stock pursuant to the employee stock purchase plan | 499 | 171 |
| Taxes paid related to net share settlement of equity awards | (53) | — |
| Net cash provided by financing activities | 48,616 | 171 |
| Net increase (decrease) in cash and cash equivalents | 78,247 | (44,889) |
| Cash and cash equivalents, beginning of period | 47,379 | 92,268 |
| Cash and cash equivalents, end of period | $ 125,626 | $ 47,379 |
| Supplemental disclosures of non-cash investing and financing activities: | | |
| Unpaid amounts for direct offering costs | $ 339 | $ — |
| Deferred offering cost paid in prior period | $ 251 | $ — |
| Unpaid amounts related to purchase of property and equipment | $ 71 | $ — |
| Operating lease liabilities recognized for operating right-of-use assets | $ — | $ 5,447 |
| Operating right-of-use assets exchanged for operating lease liabilities | $ — | $ 2,945 |

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 biotechnology company pioneering the development of dual-sided fusion proteins, including its Agonist Redirected Checkpoint ("ARC®") platform, as an entirely new class of biologic medicine capable of multifunctional activity with potential applications in oncology and autoimmune and inflammatory diseases, and other therapeutic areas. 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 $306.3 million as of December 31, 2023. 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 $130.6 million as of December 31, 2023 are sufficient to fund projected operations of the Company for at least the next twelve months.

### *Global Economic Considerations*

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, financial institution instability, instability in the geopolitical environment, 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 the Company's 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.

All of the Company's revenue in 2023 and 2022 was derived from a collaboration agreement with ImmunoGen, Inc. ("ImmunoGen") and a collaboration agreement with another third-party pharmaceutical company. In February 2024, ImmunoGen was acquired by AbbVie, Inc.

The Company is highly dependent on a limited number of contract development and manufacturing organizations ("CDMOs") to supply drug products for its research and development activities of its programs, including 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 $4.8 million held in operating accounts, $81.1 million held in money market funds and $39.7 million in U.S. Government Securities as of December 31, 2023 and $3.5 million held in operating accounts and $43.9 million held in money market funds as of December 31, 2022.

***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, 2023 and 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 years ended December 31, 2023 and 2022, the Company recorded $0.3 million and $0.7 million, respectively, of impairment losses related to lab equipment that was determined to no longer be needed, which is included in the Company's research and development costs.

***Leases***

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

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

***Pre-Funded Warrants***

The Company's pre-funded warrants are classified as a component of permanent stockholders' equity within additional paid-in capital and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants are

equity classified because they (i) are freestanding financial instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value.

***Stock-Based Compensation***

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

***Income Taxes***

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

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

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

***Net Loss Per Share***

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

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding as of December 31, 2023 and 2022, as they would be anti-dilutive:

| | As of December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Stock options | 4,942,164 | 4,209,255 |
| Unvested restricted stock units | 590,403 | 309,477 |
| | 5,532,567 | 4,518,732 |

***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***

There were no recently issued accounting statements expected to have a material impact on the Company.

**3. Investments**

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

| | December 31, 2023 | | |
|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gain | Total Fair Value |
| Investments: | | | |
| U.S. government securities | $ 4,998 | $ 1 | $ 4,999 |
| Cash Equivalents: | | | |
| U.S. government securities | 39,657 | 3 | 39,660 |
| Total level 1 debt securities | $ 44,655 | $ 4 | $ 44,659 |

| | December 31, 2022 | | |
|---|---|---|---|
| | Amortized Cost | Gross Unrealized Loss | Total Fair Value |
| Investments: | | | |
| U.S. government securities | $ 114,778 | $ (877) | $ 113,901 |
| Cash Equivalents: | | | |
| U.S. government securities | — | — | — |
| Total level 1 debt securities | $ 114,778 | $ (877) | $ 113,901 |

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 0.15 years as of December 31, 2023.

**4. Property and Equipment**

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Lab equipment | $ 15,469 | $ 15,547 |
| Leasehold improvements | 7,097 | 7,086 |
| Furniture and fixtures | 452 | 452 |
| Office equipment | 192 | 191 |
| Construction in progress | 100 | 104 |
| Property and equipment, gross | 23,310 | 23,380 |
| Less: Accumulated depreciation and amortization | (9,506) | (5,709) |
| Property and equipment, net | $ 13,804 | $ 17,671 |

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $4.0 million and $3.1 million, respectively.

## 5. Accrued Expenses

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Research and development contract costs | $ 4,235 | $ 11,256 |
| Compensation and related benefits | 3,794 | 3,967 |
| Lease liabilities | 796 | 701 |
| Litigation settlement | — | 1,400 |
| Other current liabilities | 1,041 | 471 |
| Total accrued expenses and other current liabilities | $ 9,866 | $ 17,795 |

## 6. Leases

***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):

| | December 31, | |
|---|---|---|
| Balance Sheet Classification | 2023 | 2022 |
| Other assets | $ 2,271 | $ 2,635 |
| | | |
| Accrued expenses and other current liabilities | $ 796 | $ 701 |
| Non-current operating lease liabilities | 3,406 | 4,202 |
| Total liabilities | $ 4,202 | $ 4,903 |

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Lease term (years) | 4.5 | 5.5 |
| Discount rate | 8.6 % | 8.6 % |

The Company incurred rent expense for its operating leases of $0.8 million for the years ended December 31, 2023 and 2022, respectively, which is included within operating expenses in the statements of operations and comprehensive loss. Cash paid for amounts included in the measurement of operating lease liabilities for the year ended December 31, 2023 and 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, 2023 were as follows (in thousands):

| | | |
|---|---|---|
| 2024 | $ | 1,120 |
| 2025 | | 1,152 |
| 2026 | | 1,093 |
| 2027 | | 848 |
| 2028 | | 873 |
| Thereafter | | — |
| Total lease payments | $ | 5,086 |
| Less: | | |
| Imputed interest | | (884) |
| Total | $ | 4,202 |

**7. Commitments and Contingencies**

***Kopfkino License Agreement***

The Company is party to an Exclusive License Agreement ("the Kopfkino License Agreement"), with Kopfkino IP, LLC ("Kopfkino"). Under terms of the Kopfkino License Agreement the Company is required to make payments of up to $20.5 million in aggregate for the achievement of specified development, regulatory and commercial sales milestones for certain licensed products. The Company is required to pay Kopfkino 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 Kopfkino 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. The Company originally entered into the Kopfkino License Agreement in June 2016 with Scorpius Holdings, Inc., ("Scorpius") (f/k/a Nighthawk Biosciences, Inc., f/k/a Heat Biologics Inc.). In January 2024, Scorpius assigned the rights, title, and interest in and under the agreement, along with the underlying patents and patent applications, to Kopfkino.

***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 the Company 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 cited the volatility in the Company's common stock and alleged that the defendants made or were responsible for misleading omissions regarding the Company's clinical trial results and the collaboration agreement with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company, Ltd. The court approved the parties' settlement of the plaintiffs' claims in the amount of $1.4 million and entered a final judgment dismissing the class action claims with prejudice on November 6, 2023. The Company paid the amount to the escrow agent for the settlement on June 19, 2023.

***Contractual Obligations***

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

**8. Collaboration Agreements**

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

In 2022 the Company entered into a collaboration agreement with ImmunoGen. Pursuant to the collaboration agreement, ImmunoGen will reimburse the Company for $2.0 million of the costs we incur in the Phase 1B combination cohort evaluating SL-172154 in combination with mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer. The Company dosed its first patient with mirvetuximab soravtansine in 2023 and recognized $1.7 million of revenue under the collaboration agreement in 2023. In February 2024, ImmunoGen was acquired by AbbVie, Inc. In 2022, the Company also executed and completed a collaboration agreement with a third party and recognized $0.7 million in revenue.

On February 13, 2024, we entered into a collaboration and license agreement (the "Ono Agreement") with Ono Pharmaceutical Co., Ltd ("Ono") pursuant to which the parties will collaborate in the research and preclinical development of certain prespecified compounds directed toward a pair of targets selected by Ono from our pipeline of bifunctional fusion proteins. Pursuant to the Ono Agreement, the Company granted to Ono an exclusive option (the "Option") to enter into an exclusive license to further develop, manufacture and sell products containing these bifunctional fusion proteins.

Pursuant to the Ono Agreement, the Company and Ono developed a nonclinical research plan (the "Research Plan"). The Company is primarily responsible for carrying out the research activities in accordance with the Research Plan, subject to the oversight of a joint research committee consisting of representatives from each party. Ono is responsible for all research costs incurred under the Research Plan.

Pursuant to the Ono Agreement, Ono will pay the Company $5.4 million to secure the Option and to cover the first six months of expected research costs under the Research Plan.

In addition to further Research Plan funding, the Company is entitled to receive from Ono up to $224.5 million in aggregate consisting of license fees and milestone payments based on the achievement of specified development, regulatory, and sales milestones. The company may receive tiered royalties on product sales, ranging from mid-single digit to low-double digit percentages.

Ono may terminate the Collaboration Agreement at any time upon 90 days' written notice to us. If Ono exercises such termination right, Ono will pay all of our costs up through the date of termination.

**9. Equity**

The Company is authorized to issue up to 300,000,000 shares of common stock and 10,000,000 shares of preferred stock, all with a par value of $0.0001 per share. The holders of the Company's common stock are entitled to one vote per share on all matters submitted to a vote of stockholders. The Company's common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of the Company's common stock will receive ratably any dividends declared by the Company's board of directors ("Board") out of funds legally available. In the event of the Company's liquidation, dissolution or winding-up, the holders of the Company's common stock will be entitled to share ratably in all assets remaining after payment of or provision for any liabilities. As of the periods presented, no common stock dividends had been declared by the Board. At December 31, 2023, none of the 10,000,000 shares of preferred stock were outstanding, and the Company has no present plans to issue any shares of preferred stock.

On December 26, 2023, the Company sold 4,651,163 shares of common stock through an underwritten public offering, and concurrently completed a private placement of 3,100,823 pre-funded warrants for net proceeds of $47.6 million. The purchase price per share of common stock was $6.45, and the purchase price per pre-funded warrant was $6.4499 which was the purchase price per share of common stock, minus the $0.0001 per share exercise price of such pre-funded warrant. Each pre-funded warrant may be exercised for one share of common stock, is immediately exercisable, does not expire, and is subject to a beneficial ownership limitation of 9.99% post-exercise. As of December 31, 2023, no pre-funded warrants have been exercised, and 3,100,823 pre-funded warrants remain outstanding.

In July 2022, the Company entered into a sales agreement (the "Sales Agreement") with SVB Securities LLC (the "Sales Agent"), pursuant to which it may offer and sell up to $75.0 million of shares of its common stock from time to time (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, 2023, there were no sales pursuant to the ATM Facility.

**10. Stock-Based Compensation and Employee Benefit Plans**

***2020 Equity Incentive Plan***

In September 2020, the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan") which, as of the adoption date, replaced the 2016 Stock Incentive Plan. Under the 2020 Plan, the share reserve automatically increases on January 1st of each year beginning in 2021 and ending with a final increase on January 1, 2030 in an amount equal to 4% of the Company's outstanding common stock on December 31st of the preceding calendar year. The Board may provide that there will be no increase in the share reserve for any such year or that the increase in the share reserve may be smaller than would otherwise occur. As of December 31, 2023, there were 3,983,756 shares of common stock available for future grants. On January 1, 2024, the share reserve automatically increased by 1,890,404 shares. The 2020 Plan permits the granting of options, stock appreciation rights, RSUs, performance stock, and performance cash awards. The terms of the agreements under the 2020 Plan are determined by the Board. The Company's awards generally vest over four years and have a term of 10 years. In 2023, the Company granted 165,050 options that vest in equal tranches based on the Company achieving a closing share price of equal to or greater than $4.00, $5.00, and $6.00 for 30 consecutive trading days on or before the fourth anniversary of the grant date. In 2022, the Company granted 178,150 options 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.

***2020 Employee Stock Purchase Plan***

The 2020 Employee Stock Purchase Plan (the"2020 ESPP") became effective in connection with the Company's initial public offering ("IPO") and as of December 31, 2023, a total of 1,204,874 shares of common stock are 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, 2024, the share reserve increased by 472,601 shares of common stock. During the years ended December 31, 2023 and 2022, the Company issued 23,020 and 13,088 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, | |
|---|---|---|
| | 2023 | 2022 |
| Research and development | $ 3,462 | $ 3,574 |
| General and administrative | 3,477 | 2,888 |
| Total stock-based compensation | $ 6,939 | $ 6,462 |

The following table summarizes option activity under the 2020 Plan:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Life (Years) |
|---|---|---|---|
| Balance at December 31, 2022 | 4,209,255 | $ 8.29 | 8.07 |
| Granted | 1,462,535 | 3.41 | |
| Exercised | (135,254) | 3.26 | |
| Forfeited | (594,372) | 6.41 | |
| Balance at December 31, 2023 | 4,942,164 | $ 7.21 | 7.62 |
| Vested and expected to vest | 4,787,518 | $ 7.27 | 7.47 |
| Exercisable at the end of the period | 2,696,018 | $ 8.34 | 6.47 |

Options granted during the years ended December 31, 2023 and 2022 had weighted-average grant-date fair values of $2.50 and $4.03 per share, respectively. As of December 31, 2023, the unrecognized compensation cost for options issued was $8.0 million and will be recognized over an estimated weighted-average amortization period of 1.94 years. The total intrinsic

value of options exercised during the years ended December 31, 2023 and 2022 was $0.40 million and $0.1 million, respectively. The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2023 was $6.6 million.

***Restricted Stock Units***

The following table summarizes employee RSU activity for the year ended December 31, 2023:

| | Awards | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested RSUs at December 31, 2022 | 309,477 | $ 7.22 |
| Granted | 460,925 | 3.54 |
| Vested | (77,312) | 7.22 |
| Forfeited | (102,687) | 4.62 |
| Balance at December 31, 2023 | 590,403 | $ 4.80 |

The Company recognized $0.8 million and $0.6 million of stock-based compensation related to RSUs as of December 31, 2023 and December 31, 2022. As of December 31, 2023, the unrecognized compensation cost for RSUs issued was $2.0 million and will be recognized over an estimated weighted-average amortization period of 2.70 years. The fair values of RSUs is based on the fair value of the Company's common stock on the date of the grant.

***Fair Value of Stock Options and Shares Issued***

The Company accounts for stock-based compensation by measuring and recognizing as compensation expense the fair value of all share-based payment awards made to employees, including employee stock options and restricted stock awards. The Company uses the Black-Scholes option pricing model to estimate the fair value of employee stock options that only have service or performance conditions. The 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, | |
|---|---|---|
| | 2023 | 2022 |
| **2020 Plan** | | |
| Expected term - years | 6.08 | 6.08 |
| Expected volatility | 84.8 % | 82.4 % |
| Risk-free interest rate | 3.6 % | 2.4 % |
| 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, | |
|---|---|---|
| | 2023 | 2022 |
| **2020 Plan** | | |
| Expected term - years | 4.00 | 4.00 |
| Expected volatility | 80.0 % | 80.0 % |
| Risk-free interest rate | 3.6 % | 1.4 % |
| Expected dividends | — | — |

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

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **2020 ESPP** | | |
| Expected term - years | 0.5 | 0.5 |
| Expected volatility | 85.5 % | 82.9 % |
| Risk-free interest rate | 4.0 % | 2.5 % |
| Expected dividends | — | — |

***Employee Benefit Plans***

The Company sponsors a 401(k) retirement plan in which substantially all of its full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. The Company made matching contributions of $0.7 million and $0.5 million to the plan for the years ended December 31, 2023 and 2022, respectively.

**11. Income Taxes**

The Company recorded no federal provision for income taxes as of December 31, 2023 and 2022 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, 2023 and 2022 (amounts in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Income tax benefit computed at federal statutory tax rate | $ (18,332) | $ (21,409) |
| Change in valuation allowance | 21,347 | 24,713 |
| General business credits | (4,392) | (4,883) |
| Stock compensation | 486 | 602 |
| Change in uncertain tax position | 878 | 977 |
| Other | 13 | — |
| Income tax benefit | $ — | $ — |

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Deferred tax asset: | | |
| Net operating loss carryforwards | $ 31,393 | $ 24,867 |
| Accrued expenses and other | 1,827 | 3,578 |
| Stock compensation | 2,431 | 1,533 |
| Credit carryforwards | 13,614 | 10,101 |
| Capital loss carryforwards | 583 | 583 |
| Capitalized R&D expense | 27,210 | 15,017 |
| Lease liabilities | 882 | 1,030 |
| Gross deferred tax asset | 77,940 | 56,709 |
| Less valuation allowance | (76,386) | (55,044) |
| Net deferred tax asset | 1,554 | 1,665 |
| Deferred tax liability: | | |
| Depreciation and amortization | (744) | (676) |
| Prepaid expenses | (334) | (436) |
| Lease assets | (476) | (553) |
| Total deferred tax liability | (1,554) | (1,665) |
| 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 $21.3 million and $24.7 million during the years ended December 31, 2023 and 2022, respectively, primarily due to continuing loss from operations, general business credit carryforwards, and accrued expenses.

As of December 31, 2023 and 2022, the Company had gross U.S. net operating loss ("NOL") carryforwards of $149.5 million and $118.4 million, respectively. Additionally, as of December 31, 2023 and 2022, the Company had capital loss carryforwards of $2.8 million. As of December 31, 2023 and 2022, the Company had gross state NOL carryforwards of $0.2 million. As of December 31, 2023 and 2022, the Company had gross U.S. tax credit carryforwards of $16.9 million and $12.5 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 the Company's liability for unrecognized tax benefits is as follows (amounts in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Balance, beginning of the year | $ 2,380 | $ 1,404 |
| Increase for tax positions related to the current year | 642 | 733 |
| Increase for tax positions related to prior years | 236 | 243 |
| Balance, end of year | $ 3,258 | $ 2,380 |

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, 2023, 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 2020, 2021, and 2022 tax years. There are currently no federal or state income tax audits in progress.

**12. Subsequent Events**

See Note 8 regarding the Ono Agreement entered into on February 13, 2024.

**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, 2023, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) 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, 2023, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

**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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

**Trading Plans**

During the quarter ended December 31, 2023, no director or officer adopted or terminated any Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K).

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

None.

**Part III.**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2024 Annual Meeting of Stockholders ("2024 Proxy Statement") to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, including under the headings "Information Regarding Director

Nominees and Continuing Directors," "Corporate Governance," "Executive Officers," and, as applicable, "Delinquent Section 16(a) Reports."

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is available on our website located at ir.shattucklabs.com, under "Governance." We intend to disclose on our website 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 2024 Proxy Statement, including under the headings "Executive Compensation" 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 2024 Proxy Statement, including under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

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

The information required by this item is incorporated herein by reference to our 2024 Proxy Statement, including under the headings "Corporate Governance" and "Certain Relationships and Related Party Transactions."

**Item 14. Principal Accountant Fees and Services**

The information required by this item is incorporated herein by reference to our 2024 Proxy Statement, including under the heading "Proposal 2: Ratification of Selection of Independent Auditor Selection."

## Part IV.

### Item 15. Exhibits and Financial Statement Schedules

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

(a) Financial Statements.

See Index to 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. 1 to Registration Statement on Form S-1 filed on October 05, 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 Registration Statement on Form S-1 filed on September 18, 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 (Commission File No.: 001-39593). |
| 4.4 | Form of Pre-Funded Warrant (incorporated by reference from Exhibit 4.1 of the Company's Current Report on Form 8-K filed on December 22, 2023 (Commission File No. 001-39593)) |
| 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)). |
| 10.2+ | Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Taylor Schreiber (incorporated by reference from Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)). |
| 10.3+ | Amendment No. 1 to Employment Agreement, dated March 27, 2020, by and between Shattuck Labs, Inc. and Taylor Schreiber (incorporated by reference from Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)). |
| 10.4+ | Amendment No. 2 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Taylor Schreiber (incorporated by reference from Exhibit 10.6 of the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)) |
| 10.5+ | Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Arundathy Nirmalini Pandite (incorporated by reference from Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)). |
| 10.6+ | Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Arundathy Nirmalini Pandite (incorporated by reference from Exhibit 10.8 of the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)) |
| 10.07+ | Employment Agreement, dated December 5, 2019, by and between Shattuck Labs, Inc. and Andrew R. Neill (incorporated by reference from Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on September 18, 2020 (Commission File No. 333-248918)). |

| | |
|---|---|
| 10.08+ | Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Andrew R. Neill (incorporated by reference from Exhibit 10.12 of The Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)) |
| 10.09+ | Employment Agreement, dated December 9, 2019, by and between Shattuck Labs, Inc. and Casi DeYoung (incorporated by reference from Exhibit 10.13 of the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)) |
| 10.10+ | Amendment No. 1 to Employment Agreement, dated March 12, 2021, by and between Shattuck Labs, Inc. and Casi DeYoung (incorporated by reference from Exhibit 10.14 of the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)) |
| 10.11+ | Employment Agreement, dated June 1, 2021, by and between Shattuck Labs, Inc. and Abhinav Shukla |
| 10.12+ | 2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.9 of the Company's Amendment No. 1 to Registration Statement on Form S-1 filed on October 5, 2020 (Commission File No. 333-248918)). |
| 10.13+ | 2020 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.10 of the Company's Amendment No. 1 to Registration Statement on Form S-1 filed on October 5, 2020 (Commission File No. 333-248918)). |
| 10.14+ | Form of Stock Option Grant Notice and Stock Option Agreement for Executives under the 2020 Employment Incentive Plan |
| 10.15+ | Form of Stock Option Grant Notice and Stock Option Agreement for Board of Directors under the 2020 Employment Incentive Plan |
| 10.16+ | Form of Restricted Stock Unit Grant Notice and Stock Option Agreement under the 2020 Employment Incentive Plan |
| 10.17+ | Non-Employee Director Compensation Policy, as Amended |
| 10.18 | 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)). |
| 10.19 | 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)). |
| 10.20† | Lease Agreement, dated January 8, 2021, between Shattuck Labs, Inc. and International Bank of Commerce, Laredo, Texas. incorporated by reference from Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on March 16, 2021 (Commission File No. 001-39593)) |
| 10.21† | 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)). |
| 10.22 | Takeda Termination Agreement (incorporated by reference from Exhibit 10.1 of Shattuck's Quarterly Report on Form 10-Q filed on November 9, 2021 (Commission File No. 001-39593)) |
| 10.23 | 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. 001-39593)) |
| 10.24 | Clinical Trial and Collaboration and Supply Agreement dated February 4, 2022 by and between Shattuck Labs, Inc, and Immunogen (incorporated by reference from Exhibit 10.25 of Shattuck's Annual Report on Form 10-K filed on February, 2023 (Commission File No. 001-39593)) |
| 10.25 | Securities Purchase Agreement, dated December 21, 2023, by and between Shattuck Labs, Inc. and each purchaser identified on Annex A thereto (incorporated by reference from Exhibit 10.1 of Shattuck's Current Report on Form 8-K filed on December 22, 2023 (Commission File No. 001-39593)) |
| 10.25 | Registration Rights Agreement, dated December 21, 2023, by and between Shattuck Labs, Inc. and the several purchasers signatory thereto (incorporated by reference from Exhibit 10.2 of Shattuck's Current Report on Form 8-K filed on December 22, 2023 (Commission File No. 001-39593)) |
| 23.1* | Consent of Independent Registered Public Accounting Firm. |
| 31.1* | Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934. |
| 31.2* | Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934. |

| | |
|---|---|
| 32.1# | Certification of the principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) under the Securities Exchange Act of 1934. |
| 97.1* | Incentive Compensation Clawback Policy |
| 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). |

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* 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 29, 2024

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

Date: February 29, 2024

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<br>Dr. Taylor Schreiber | Chief Executive Officer and Director<br>(*principal executive officer*) | February 29, 2024 |
| /s/ Andrew R. Neill<br>Andrew R. Neill | Chief Financial Officer<br>(*principal financial and accounting officer*) | February 29, 2024 |
| /s/ Dr. George Golumbeski<br>Dr. George Golumbeski | Chairman of the Board | February 29, 2024 |
| /s/ Helen M. Boudreau<br>Helen M. Boudreau | Director | February 29, 2024 |
| /s/ Dr. Neil Gibson<br>Dr. Neil Gibson | Director | February 29, 2024 |
| /s/ Dr. Carrie Brownstein<br>Dr. Carrie Brownstein | Director | February 29, 2024 |
| /s/ Michael Lee<br>Michael Lee | Director | February 29, 2024 |
| /s/ Tyler Brous<br>Tyler Brous | Director | February 29, 2024 |

500 W. 5th Street, Suite 1200, Austin, Texas 78701

**NOTICE OF THE 2024 ANNUAL MEETING OF STOCKHOLDERS**
**TO BE HELD ON JUNE 7, 2024**

To the Stockholders of Shattuck Labs:

Shattuck Labs, Inc. (the "Company") will hold its 2024 Annual Meeting of Stockholders (the "Annual Meeting") on Friday, June 7, 2024 at 11:30 a.m. Eastern Time. The Annual Meeting will be a virtual meeting conducted exclusively online via live audio webcast at the unique link that will be emailed to you approximately one hour prior to the meeting after you register in advance. The Annual Meeting will be held for the following purposes, as more fully described in the accompanying proxy statement (the "Proxy Statement"):

(1) To elect the three Class I director nominees named in the Proxy Statement to serve until the 2027 Annual Meeting of Stockholders and until their successors are duly elected and qualified;

(2) To ratify the selection of KPMG LLP as the Company's independent registered public accounting firm for the year ending December 31, 2024; and

(3) To transact any other matters that may properly come before the Annual Meeting or any adjournments or postponements thereof.

The Board of Directors has fixed April 11, 2024 as the record date. Only stockholders of record at the close of business on that date will be entitled to notice of, and to vote at, the Annual Meeting or any adjournment or postponement thereof.

Instructions for registering for and accessing the virtual Annual Meeting are provided in the Proxy Statement. In the event of a technical malfunction or other situation that the meeting chair determines may affect the ability of the Annual Meeting to satisfy the requirements for a meeting of stockholders to be held by means of remote communication under the Delaware General Corporation Law, or that otherwise makes it advisable to adjourn the Annual Meeting, the meeting chair or secretary will convene the meeting at 12:30 p.m. Eastern Time on the date specified above and at the Company's address specified above solely for the purpose of adjourning the meeting to reconvene at a date, time and physical or virtual location announced by the meeting chair or secretary. Under either of the foregoing circumstances, we will post information regarding the announcement on the Investors page of the Company's website at *ir.shattucklabs.com*.

By Order of the Board of Directors,

/s/ Dr. Taylor Schreiber

Dr. Taylor Schreiber
Chief Executive Officer and Director

Austin, Texas
April 23, 2024

**Whether or not you expect to participate in the virtual Annual Meeting, please vote as promptly as possible in order to ensure your representation at the Annual Meeting. You may vote online or, if you requested printed copies of the proxy materials, by telephone or by using the proxy card or voting instruction form provided with the printed proxy materials.**

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## LEGAL MATTERS

***Important Notice Regarding the Availability of Proxy Materials for the 2024 Annual Meeting of Stockholders to Be Held on June 7, 2024.*** The Proxy Statement and Annual Report for the year ended December 31, 2023 are available at *www.proxydocs.com/STTK*.

***Forward-Looking Statements.*** The Proxy Statement may contain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact included in the Proxy Statement, including statements about the Company's Board of Directors, corporate governance practices, executive compensation program and equity compensation utilization, 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. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in the Proxy Statement. Such risks, uncertainties and other factors include those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") and other subsequent documents we file with the SEC. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

***Website References.*** Website references throughout this document are inactive textual references and provided for convenience only, and the content on the referenced websites is not incorporated herein by reference and does not constitute a part of the Proxy Statement.

***Use of Trademarks.*** Shattuck Labs is the trademark of Shattuck Labs, Inc. Other names and brands may be claimed as the property of others.

500 W. 5th Street, Suite 1200, Austin, Texas 78701

**PROXY STATEMENT**
**FOR THE 2024 ANNUAL MEETING OF STOCKHOLDERS**

## QUESTIONS AND ANSWERS ABOUT THE PROXY MATERIALS AND VOTING

### What Is the Purpose of These Proxy Materials?

We are making these proxy materials available to you in connection with the solicitation of proxies by the Board of Directors (the "Board") of Shattuck Labs, Inc. ("we," "us," "our" or the "Company") for use at the 2024 Annual Meeting of Stockholders (the "Annual Meeting") to be held virtually on Friday, June 7, 2024 at 11:30 a.m. Eastern Time, or at any other time following adjournment or postponement thereof. You are invited to participate in the Annual Meeting and to vote on the proposals described in this Proxy Statement. The proxy materials are first being made available to our stockholders on or about April 23, 2024.

### Why Did I Receive a Notice of Internet Availability?

Pursuant to U.S. Securities and Exchange Commission ("SEC") rules, we are furnishing the proxy materials to our stockholders primarily via the Internet instead of mailing printed copies. This process allows us to expedite our stockholders' receipt of proxy materials, lower the costs of printing and mailing the proxy materials and reduce the environmental impact of our Annual Meeting. If you received a Notice of Internet Availability of Proxy Materials (the "Notice"), you will not receive a printed copy of the proxy materials unless you request one. The Notice provides instructions on how to access the proxy materials for the Annual Meeting via the Internet, how to request a printed set of proxy materials and how to vote your shares.

### Why Are We Holding a Virtual Annual Meeting?

We have adopted a virtual meeting format for the Annual Meeting to provide a consistent experience to all stockholders regardless of geographic location. We believe this expands stockholder access, improves communications and lowers our costs while reducing the environmental impact of the meeting. In structuring our virtual Annual Meeting, our goal is to enhance rather than constrain stockholder participation in the meeting, and we have designed the meeting to provide stockholders with the same rights and opportunities to participate as they would have at an in-person meeting.

### Who Can Vote?

Only stockholders of record at the close of business on April 11, 2024 (the "Record Date") are entitled to notice of the Annual Meeting and to vote on the proposals described in this Proxy Statement. At the close of business on the Record Date, 47,550,872 shares of our common stock were issued and outstanding.

### What Is the Difference between Holding Shares as a Registered Stockholder and as a Beneficial Owner?

*Registered Stockholder: Shares Registered in Your Name*

If your shares of common stock are registered directly in your name with our transfer agent, Equiniti Trust Company, LLC, you are considered to be, with respect to those shares of common stock, the registered stockholder, and these proxy materials are being sent directly to you by us.

*Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian*

If your shares of common stock are held by a broker, fiduciary or custodian, you are considered the beneficial owner of shares of common stock held in "street name," and these proxy materials are being forwarded to you from that broker, fiduciary or custodian.

**How Can I Participate in the Virtual Annual Meeting?**

Stockholders of record as of the close of business on the Record Date are entitled to participate in and vote at the Annual Meeting. To participate in the Annual Meeting, including to vote, ask questions and view the list of registered stockholders as of the Record Date during the meeting, stockholders will need to register in advance following the instructions below.

We will endeavor to answer as many stockholder-submitted questions as time permits that comply with the Annual Meeting rules of conduct. We reserve the right to edit profanity or other inappropriate language and to exclude questions regarding topics that are not pertinent to meeting matters or Company business. If we receive substantially similar questions, we may group such questions together and provide a single response to avoid repetition.

The meeting webcast will begin promptly at 11:30 a.m. Eastern Time. Online check-in will begin approximately 15 minutes before then, and we encourage you to allow ample time for check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please call the technical support number that will be included in the email containing your access link to the meeting. Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which stockholders can view during the meeting at the meeting website.

*Meeting Registration Process for Registered Stockholders*

If your shares are registered directly in your name with our transfer agent, you can register for the Annual Meeting at either *www.proxydocs.com/STTK* or *www.proxypush.com/STTK* by following the instructions on the website. As part of the registration process, you will be asked to enter the control number located on your proxy card or Notice. Upon completing your registration, you will receive further instructions via email, including a unique link that will allow you to access the Annual Meeting and vote and submit questions during the Annual Meeting.

*Meeting Registration Process for Beneficial Owners*

If your shares are held in street name, you can register for the Annual Meeting at *www.proxydocs.com/STTK* by following the instructions on the website. In addition, it is important that you also follow the instructions you receive from your broker, fiduciary or custodian about participating in the Annual Meeting, which may include a requirement to obtain a legal proxy from them and submit a copy during the advance registration process for the meeting.

**What Am I Voting on?**

The proposals to be voted on at the Annual Meeting are as follows:

(1) Election of three Class I director nominees to serve until the 2027 Annual Meeting of Stockholders ("Proposal 1"); and

(2) Ratification of the selection of KPMG LLP as the Company's independent auditor for 2024 ("Proposal 2").

**How Does the Board Recommend That I Vote?**

The Board recommends that you vote your shares "**FOR**" each director nominee in Proposal 1 and "**FOR**" Proposal 2.

**What If Another Matter Is Properly Brought before the Annual Meeting?**

As of the date of filing this Proxy Statement, the Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named as proxies in the proxy card to vote on such matters in accordance with their best judgment.

**How Many Votes Do I Have?**

Each share of common stock is entitled to one vote on each proposal to be voted on at the Annual Meeting.

**What Does It Mean If I Receive More Than One Set of Proxy Materials?**

If you receive more than one set of proxy materials, your shares may be registered in more than one name or held in different accounts. Please cast your vote with respect to each set of proxy materials that you receive to ensure that all of your shares are voted.

**How Do I Vote?**

Even if you plan to attend the Annual Meeting, we recommend that you also submit your vote as early as possible in advance so that your vote will be counted if you later decide not to, or are unable to, virtually attend the Annual Meeting.

*Registered Stockholder: Shares Registered in Your Name*

If you are the registered stockholder, you may vote your shares online during the virtual Annual Meeting (see "How Can I Participate in the Virtual Annual Meeting?" above) or by proxy in advance of the Annual Meeting by Internet (at *www.proxypush.com/STTK*) or, if you requested paper copies of the proxy materials, by completing and mailing a proxy card or by telephone (at 866-870-7493).

*Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian*

If you are the beneficial owner, you may vote your shares online during the virtual Annual Meeting (see "How Can I Participate in the Virtual Annual Meeting?" above) or you may direct your broker, fiduciary or custodian how to vote in advance of the Annual Meeting by following the instructions they provide.

**What Happens If I Do Not Vote?**

*Registered Stockholder: Shares Registered in Your Name*

If you are the registered stockholder and do not vote in one of the ways described above, your shares will not be voted at the Annual Meeting and will not be counted toward the quorum requirement.

*Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian*

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, fiduciary or custodian is not entitled to vote your shares with respect to

"non-routine" proposals, which we refer to as a "broker non-vote." Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokers are choosing not to exercise discretionary voting authority. As a result, we urge you to direct your broker, fiduciary or custodian how to vote your shares on all proposals to ensure that your vote is counted.

**What If I Sign and Return a Proxy Card or Otherwise Vote but Do Not Indicate Specific Choices?**

*Registered Stockholder: Shares Registered in Your Name*

The shares represented by each signed and returned proxy will be voted at the Annual Meeting by the persons named as proxies in the proxy card in accordance with the instructions indicated on the proxy card. However, if you are the registered stockholder and sign and return your proxy card without giving specific instructions, the persons named as proxies in the proxy card will vote your shares in accordance with the recommendations of the Board. Your shares will be counted toward the quorum requirement.

*Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian*

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, fiduciary or custodian is not entitled to vote your shares with respect to "non-routine" proposals, resulting in a broker non-vote with respect to such proposals.

**Can I Change My Vote after I Submit My Proxy?**

*Registered Stockholder: Shares Registered in Your Name*

If you are the registered stockholder, you may revoke your proxy at any time before the final vote at the Annual Meeting in any one of the following ways:

(1) You may complete and submit a new proxy card, but it must bear a later date than the original proxy card;

(2) You may submit new proxy instructions via telephone or the Internet;

(3) You may send a timely written notice that you are revoking your proxy to our Corporate Secretary at the address set forth on the first page of this Proxy Statement; or

(4) You may vote by attending the Annual Meeting virtually. However, your virtual attendance at the Annual Meeting will not, by itself, revoke your proxy.

Your last submitted vote is the one that will be counted.

*Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian*

If you are the beneficial owner, you must follow the instructions you receive from your broker, fiduciary or custodian with respect to changing your vote.

**What Is the Quorum Requirement?**

The holders of a majority of the shares of common stock outstanding and entitled to vote at the Annual Meeting must be present at the Annual Meeting, either virtually or represented by proxy, to constitute a quorum. A quorum is required to transact business at the Annual Meeting.

Your shares will be counted toward the quorum only if you submit a valid proxy (or a valid proxy is submitted on your behalf by your broker, fiduciary or custodian) or if you attend the Annual Meeting virtually

and vote. Abstentions and broker non-votes will be counted toward the quorum requirement. If there is no quorum, the chairman of the Annual Meeting or the holders of a majority of shares of common stock virtually present at the Annual Meeting, either personally or by proxy, may adjourn the Annual Meeting to another time or date.

**How Many Votes Are Required to Approve Each Proposal and How Are Votes Counted?**

Votes will be counted by Mediant Communications Inc., the Inspector of Elections appointed for the Annual Meeting.

*Proposal 1: Election of Directors*

A nominee will be elected as a director at the Annual Meeting if the nominee receives a plurality of the votes cast "**FOR**" his or her election. "Plurality" means that the individuals who receive the highest number of votes cast "**FOR**" are elected as directors. Broker non-votes, if any, and votes that are withheld will not be counted as votes cast on the matter and will have no effect on the outcome of the election. Stockholders do not have cumulative voting rights for the election of directors.

*Proposal 2: Ratification of Independent Auditor Selection*

The affirmative vote of a majority of shares of common stock present or represented at the Annual Meeting and entitled to vote on the matter is required for the ratification of the selection of KPMG LLP as our independent auditor. Abstentions will have the same effect as a vote "**AGAINST**" the matter. Broker non-votes, if any, will have no effect on the outcome of the matter.

**Who Is Paying for This Proxy Solicitation?**

We will pay the costs associated with the solicitation of proxies, including the preparation, assembly, printing and mailing of the proxy materials. We may also reimburse brokers, fiduciaries or custodians for the cost of forwarding proxy materials to beneficial owners of shares of common stock held in "street name."

Our employees, officers and directors may solicit proxies in person or via telephone or the Internet. We will not pay additional compensation for any of these services.

**How Can I Find out the Voting Results?**

We expect to announce preliminary voting results at the Annual Meeting. Final voting results will be published in a Current Report on Form 8-K to be filed with the SEC within four business days after the Annual Meeting.

## PROPOSAL 1: ELECTION OF DIRECTORS

In accordance with our bylaws, the Board has fixed the number of directors constituting the Board at nine. At the Annual Meeting, the stockholders will vote to elect the three Class I director nominees named in this Proxy Statement to serve until the 2027 Annual Meeting of Stockholders and until their successors are duly elected and qualified or until their earlier resignation or removal. Our Board has nominated Tyler Brous, Dr. Carrie Brownstein and Michael Lee for election to our Board. Messrs. Brous and Lee were most recently elected by stockholders at the 2021 Annual Meeting of Stockholders. Dr. Brownstein was appointed to the Board in October 2021, and was recommended to the Board by a third-party search firm specializing in the placement of directors in the life sciences industry.

Our director nominees have indicated that they are willing and able to serve as directors. However, if any of them becomes unable or, for good cause, unwilling to serve, proxies may be voted for the election of such other person as shall be designated by our Board, or the Board may decrease the size of the class and Board.

### Information Regarding Director Nominees and Continuing Directors

Our Board is divided into three classes, with members of each class holding office for staggered three-year terms. There are currently three Class I directors, who are up for election at this meeting for a term expiring at the 2027 Annual Meeting of Stockholders; three Class II directors, whose terms expire at the 2025 Annual Meeting of Stockholders; and three Class III directors, whose terms expire at the 2026 Annual Meeting of Stockholders.

Biographical and other information regarding our director nominees and directors continuing in office, including the primary skills and experiences considered by our Nominating and Corporate Governance Committee in determining to recommend them as nominees, is set forth below.

| Name | Class | Age (as of April 23, 2024) | Position |
|---|---|---|---|
| Taylor Schreiber, M.D., Ph.D. | Class III | 44 | Chief Executive Officer and Director |
| Helen M. Boudreau[1][2] | Class III | 58 | Independent Director |
| Tyler Brous[1][2] | Class I | 41 | Independent Director |
| Carrie Brownstein, M.D.[3] | Class I | 54 | Independent Director |
| Neil Gibson, Ph.D.[1][3] | Class II | 68 | Independent Director |
| George Golumbeski, Ph.D.[2] | Class II | 67 | Independent Chairman of the Board |
| Michael Lee[3] | Class I | 45 | Independent Director |
| Kate Sasser, Ph.D. | Class II | 47 | Independent Director |
| Clay Siegall, Ph.D. | Class III | 63 | Independent Director |

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

#### *Class I Director Nominees*

***Tyler Brous.*** Mr. Brous has served on our Board since September 2016. He has worked at Lennox Capital Partners, a private equity firm, since 2011, and currently serves as its Managing Director and Portfolio Manager. He has served on the board of directors of ColdQuanta, Inc., a quantum technology company, since 2020 and previously served on the board of CerSci Therapeutics, Inc., a biotechnology company, from 2018 until its sale in 2020. Mr. Brous earned his B.S. in Finance and Business from the University of Texas, where he graduated *summa cum laude*.

We believe Mr. Brous is qualified to serve on our Board because of his extensive experience investing in and operating biotechnology companies and his financial expertise.

***Carrie Brownstein, M.D.*** Dr. Brownstein has served on our Board since October 2021. Dr. Brownstein has served as Principal at CMB BioPharma Solutions, a clinical development consultancy, since March 2024. She previously served as the Chief Medical Officer of Zentalis Pharmaceuticals, Inc. (Nasdaq: ZNTL), a biopharmaceutical company, from October 2022 to March 2024. She served as Chief Medical Officer of Cellectis S.A. (Nasdaq: CLLS), a biopharmaceutical company, from April 2020 to September 2022; Vice President of Global Clinical Research and Development, Therapeutic Area Head for Myeloid Diseases at Celgene Corp., a pharmaceutical company, from July 2017 to April 2020, Executive Director of Clinical Sciences Oncology at Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN), a biotechnology company, from August 2012 to March 2017, and Senior Medical Director of Hematology and Oncology at F. Hoffmann-La Roche AG (OTCMKTS: RHHBY), a pharmaceutical company, from September 2006 to August 2012. Prior to her industry career, Dr. Brownstein practiced pediatric hematology and oncology at New York Presbyterian Columbia University and Mount Sinai Medical Center, completed her internship and residency at Columbia Presbyterian Medical Center in New York and her subspecialty training at Memorial Sloan-Kettering Cancer Center. Dr. Brownstein earned her A.B. in Psychology from the University of Michigan and her M.D. from Tufts University School of Medicine.

We believe Dr. Brownstein is qualified to serve on our Board because of her medical expertise and extensive experience in the pharmaceuticals industry.

***Michael Lee.*** Mr. Lee has served as a member of our Board since June 2020. Mr. Lee has served as Co-Founder and Managing Director at Redmile Group, LLC, a healthcare-focused investment firm based in San Francisco and New York, since 2007. Prior to Redmile, he worked as a biotechnology investor at Steeple Capital, Welch Capital Partners and Prudential Equity Group. Mr. Lee currently serves on the board of directors of Fate Therapeutics, Inc. (Nasdaq: FATE), a clinical-stage biopharmaceutical company, and IGM Biosciences, Inc. (Nasdaq: IGMS), a biotechnology company. Mr. Lee earned his B.S. in Molecular and Cellular Biology from the University of Arizona.

We believe Mr. Lee is qualified to serve on our Board because of his industry experience and experience as an investor in biotechnology companies.

***Class II Directors Continuing in Office***

***Neil Gibson, Ph.D.*** Dr. Gibson has served as a member of our Board since November 2016. Dr. Gibson most recently served as Senior Vice President of COI Pharmaceuticals, Inc., an accelerator company focused on the creation and development of unique drug discovery companies based on innovative and disruptive technologies, from October 2016 to December 2021. Previously, he served as President and Chief Executive Officer of Adanate from 2017 to November 2021 and President and Chief Executive Officer of PDI Therapeutics from 2017 to June 2020, both COI Pharmaceuticals, Inc. companies. Dr. Gibson has also served in leadership roles at various biotechnology companies, including Senior Vice President of BioAtla, Inc. (Nasdaq: BCAB) from 2015 to 2016; Chief Scientific Officer of Regulus Therapeutics Inc. (Nasdaq: RGLS) from 2011 to 2015; Chief Scientific Officer and Oncology Therapeutic Area Head of Pfizer Oncology from 2007 to 2011; and Chief Scientific Officer of OSI Pharmaceuticals, Inc. from 2000 to 2007. While at Pfizer, Dr. Gibson was also a member of the Pfizer Oncology Business Unit Executive team. Dr. Gibson has served on the boards of TCR2 Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage cell therapy company, and Causeway Therapeutics, a clinical-stage biopharmaceutical company, since 2017, the board of Adanate, Inc., a biotechnology company, since 2022, and Instil Bio, Inc. (Nasdaq: TIL), a clinical-stage biopharmaceutical company, since June 2020. He previously served on the boards of Cullinan MICA, a biotechnology company, from 2020 to 2022, and CytoSen Therapeutics, Inc., a biopharmaceutical company, from 2016 to 2019. Dr. Gibson earned his B.Sc. in Pharmacy from the University of Strathclyde in Glasgow, Scotland and his Ph.D. from the University of Aston in Birmingham, England.

We believe Dr. Gibson is qualified to serve on our Board because of his extensive experience as an executive officer in the biopharmaceutical industry, including his technical expertise related to drug discovery and development.

***George Golumbeski, Ph.D.*** Dr. Golumbeski has served as a member of our Board since January 2018 and as our Chairman since October 2021. He has more than 30 years of experience in the biotechnology industry. He has served as a partner at Droia Genetic Disease Fund, a life sciences investment firm, since October 2020. From August 2018 to August 2019, he served as President of GRAIL, Inc., an oncology-focused healthcare company. From March 2009 to April 2018, Dr. Golumbeski served as the Executive Vice President of Business Development of Celgene Corp., an oncology and immunology-focused pharmaceutical company, where he was responsible for forging collaborations with biotechnology companies seeking to bring breakthrough medications to people suffering from cancer and chronic inflammation. He currently serves on the board of directors of several biotechnology companies, including MorphoSys AG (Nasdaq: MOR), Sage Therapeutics, Inc. (Nasdaq: SAGE) and Carrick Therapeutics. He previously served on the boards of Enanta Pharmaceuticals Inc. (Nasdaq: ENTA) and Aura Biosciences, Inc. (Nasdaq: AURA). Dr. Golumbeski earned his B.S. in Biology from the University of Virginia and his Ph.D. in Genetics from the University of Wisconsin-Madison, and he conducted his post-doctoral research in molecular biology at the University of Colorado-Boulder.

We believe Dr. Golumbeski is qualified to serve on our Board because of his extensive management experience and service on the boards of directors of numerous biotechnology companies as well as his experience with mergers and acquisitions and in developing biopharmaceutical collaborations and partnerships.

***A. Kate Sasser, Ph.D.*** Dr. Sasser has served as a member of our Board since March 2024. She has served as the Chief Scientific Officer of Tempus AI, a healthcare technology company, since October 2022. From July 2016 to October 2022, Dr. Sasser served as Corporate Vice President at Genmab A/S (Nasdaq: GMAB), a biotechnology company. From 2009 to 2016, she served in various roles at Johnson and Johnson Innovative Medicine (formerly Janssen Pharmaceuticals Companies), a pharmaceutical company, including most recently as Vice President overseeing translational research for oncology. Dr. Sasser earned her B.S. from Oregon State University and her Ph.D. in Integrated Biomedical Sciences from the Ohio State University.

We believe Dr. Sasser is qualified to serve on our Board because of her extensive experience leading biotechnology companies.

***Class III Directors Continuing in Office***

***Helen M. Boudreau.*** Ms. Boudreau has served as a member of our Board since July 2020. Ms. Boudreau has over 30 years of experience across the biotechnology, pharmaceutical, consulting and banking industries. She currently serves as managing director at Estuary Ventures LLC, a board and advisory services company. From June 2018 to June 2019, she was Chief Operating Officer of the Bill & Melinda Gates Medical Research Institute, a nonprofit biotechnology company. Previously, she served as Chief Financial Officer from July 2017 to June 2018 and board member from February 2016 to July 2017 for Proteostasis Therapeutics, Inc., a clinical-stage biopharmaceutical company. From October 2014 to June 2017, she served as Chief Financial Officer for FORMA Therapeutics, Inc., a biopharmaceutical company acquired by Novo Nordisk A/S. Ms. Boudreau spent 16 years at Novartis AG (NYSE: NVS) and Pfizer Inc. (NYSE: PFE) in progressively senior finance and strategy roles, and worked earlier in her career at McKinsey & Company and Bank of America (NYSE: BAC). She is currently a member of the board of directors of Premier, Inc. (Nasdaq: PINC), a healthcare improvement company, Rallybio Corp. (Nasdaq: RLYB), a biopharmaceutical company, and Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company. She was previously a member of the board of Reunion Neuroscience (Nasdaq: REUN), a biopharmaceutical company, from 2020 to 2023 and Evaxion Biotech A/S (Nasdaq: EVAX), a clinical-stage AI-immunology platform company, from 2020 to 2021. Ms. Boudreau earned her B.A. in Economics from the University of Maryland, where she graduated *summa cum laude*, and her M.B.A. from the Darden Graduate School of Business at the University of Virginia. Ms. Boudreau is Directorship Certified™ by the NACD and earned the CERT Certificate in Cyber-Risk Oversight from Carnegie Mellon University Software Engineering Institute.

We believe Ms. Boudreau is qualified to serve on our Board because of her financial expertise and extensive experience with biotechnology companies.

***Taylor Schreiber, M.D., Ph.D.*** Dr. Schreiber is a co-founder of Shattuck Labs. He served as our Chief Scientific Officer from January 2017 until January 2020, when he became our Chief Executive Officer, and has been a member of our Board since 2017. Dr. Schreiber is the lead inventor of Shattuck Labs' ARC and GADLEN technology platforms. From March 2014 to July 2015, Dr. Schreiber served as Vice President of Research & Development of Heat Biologics, Inc. (now NightHawk Biosciences (NYSE: NHWK)), an immunotherapy-focused biotechnology company, and subsequently served as Chief Scientific Officer of Heat Biologics until December 2016. From January 2011 to March 2017, he also served as Chairman of the Scientific Advisory Board of Pelican Therapeutics, Inc., an immunotherapy company. Dr. Schreiber earned his B.A. in Biology from Bucknell University and his M.D. and Ph.D. from the Sheila and David Fuente Program in Cancer Biology at the University of Miami Miller School of Medicine.

We believe Dr. Schreiber is qualified to serve on our Board because of his extensive experience in the biopharmaceutical industry.

***Clay Siegall, Ph.D.*** Dr. Siegall has served as a member our Board since March 2024. He has served as President, Chief Executive Officer and Chairman of the board of directors of Immunome, Inc. (Nasdaq: IMNM), a biotechnology company, since October 2023. Prior to joining Immunome, from January 2023 to October 2023, he served as the President and Chief Executive Officer of MorphImmune, Inc., a biotechnology company that merged with Immunome. Dr. Siegall co-founded Seagen Inc. (formerly Seattle Genetics), a biotechnology company acquired by Pfizer Inc., in January 1998 and served in various leadership roles, including as Chief Executive Officer, from November 2002 to May 2022, President, from June 2000 to May 2022, and Chairman of the board of directors, from March 2004 to May 2022. In addition to Immunome, he currently serves on the board of directors of Tourmaline Bio, Inc. (Nasdaq: TRML), a biotechnology company. He previously served on the board of directors of Nurix Therapeutics, Inc. (Nasdaq: NRIX), from June 2021 to May 2022, Ultragenyx Pharmaceutical Inc. (Nasdaq: RARE), from February 2014 to June 2021, and Alder BioPharmaceuticals, Inc., from 2006 to October 2019. Dr. Siegall earned his B.S. in Zoology from the University of Maryland and his Ph.D. in Genetics from George Washington University.

We believe Dr. Siegall is qualified to serve on our Board because of his extensive experience leading biotechnology companies and his experience serving on the boards of directors of public companies.

**Board Recommendation**

The Board recommends a vote "**FOR**" all Class I director nominees set forth above.

## PROPOSAL 2: RATIFICATION OF INDEPENDENT AUDITOR SELECTION

Our Audit Committee has selected KPMG LLP ("KPMG") as the Company's independent registered public accounting firm for the year ending December 31, 2024. In this Proposal 2, we are asking stockholders to vote to ratify this selection. Representatives of KPMG are expected to be present at the Annual Meeting. They will have the opportunity to make a statement, if they desire to do so, and are expected to be available to respond to appropriate questions from stockholders.

Stockholder ratification of the selection of KPMG as the Company's independent auditor is not required by law or our bylaws. However, we are seeking stockholder ratification as a matter of good corporate practice. If our stockholders fail to ratify the selection, the committee will reconsider its selection. Even if the selection is ratified, the committee, in its discretion, may direct the selection of a different independent auditor at any time during the year if it determines that such a change would be in the best interests of the Company and our stockholders.

KPMG has served as our independent auditor since 2018. The following table summarizes the audit fees billed and expected to be billed by KPMG for the indicated fiscal years and the fees billed by KPMG for all other services rendered during the indicated fiscal years. All services associated with such fees were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described below.

| | Year Ended December 31, | |
|---|---|---|
| **Fee Category** | **2023** | **2022** |
| Audit Fees[1] | $640,902 | $581,586 |
| Audit-Related Fees[2] | — | — |
| Tax Fees[3] | — | — |
| All Other Fees[4] | — | — |
| Total Fees | $640,902 | $581,586 |

(1) Consists of fees for the audit of our annual financial statements, reviews of quarterly financial statements and services provided in connection with SEC filings, including consents and comment and comfort letters.
(2) Consists of fees for assurance and related services reasonably related to the performance of the audit or review of our financial statements.
(3) Consists of fees for professional services for tax compliance, tax advice and tax planning.
(4) Consists of fees for all other services.

### Pre-Approval Policies and Procedures

Our Audit Committee has adopted procedures requiring the pre-approval of all audit and non-audit services performed by our independent auditor in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the committee for each engagement of our auditor to perform other audit-related or other non-audit services. The committee does not delegate its responsibility to approve services performed by our auditor to any member of management. The committee has delegated authority to the committee chair to pre-approve any audit or non-audit service to be provided to us by our auditor provided that the fees for such services do not exceed $100,000. Any approval of services by the committee chair pursuant to this delegated authority must be reported to the committee at its next regularly scheduled meeting.

### Report of the Audit Committee

The Audit Committee has reviewed and discussed the audited financial statements for the year ended December 31, 2023 with the Company's management and with KPMG, the Company's independent registered

public accounting firm. The Audit Committee has discussed with KPMG the matters required to be discussed by the applicable standards of the Public Company Accounting Oversight Board ("PCAOB") and the SEC. The Audit Committee has also received the written disclosures and the letter from KPMG pursuant to applicable PCAOB requirements regarding its communications with the Audit Committee concerning independence, and the Audit Committee has discussed with KPMG its independence. Based on the foregoing, the Audit Committee recommended to the Board that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 for filing with the SEC.

This report is provided by the following directors, who serve on the Audit Committee:

Helen M. Boudreau (Chair)
Tyler Brous
Neil Gibson, Ph.D.

**Board Recommendation**

The Board recommends a vote "**FOR**" the ratification of the selection of KPMG to serve as our independent auditor.

## CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board. Our Board has adopted a set of Principles of Corporate Governance as a framework for the governance of the Company, which is posted on our website located at *ir.shattucklabs.com*, under "Governance."

### Board Composition

*Director Nomination Process*

The Nominating and Corporate Governance Committee is responsible for, among other things, overseeing succession planning for directors and building a qualified board to oversee management's execution of the Company's strategy and safeguard the long-term interests of stockholders. In this regard, the committee is charged with developing and recommending Board membership criteria to the Board for approval, evaluating the composition of the Board annually to assess the skills and experience that are currently represented on the Board and the skills and experience that the Board may find valuable in the future, and identifying, evaluating and recommending potential director candidates.

In identifying potential candidates for Board membership, the Nominating and Corporate Governance Committee considers recommendations from directors, stockholders, management and others, including, from time to time, third-party search firms, which it engaged in 2023, to assist it in locating qualified candidates. Once potential director candidates are identified, the committee, with the assistance of management, undertakes a vetting process that considers each candidate's background, independence and fit with the Board's priorities. As part of this vetting process, the committee, as well as other members of the Board and the CEO, may conduct interviews with the candidates. If the committee determines that a potential candidate meets the needs of the Board and has the desired qualifications, it recommends the candidate to the full Board for appointment or nomination and to the stockholders for election at the annual meeting.

*Criteria for Board Membership*

In assessing potential candidates for Board membership and in assessing Board composition, the Nominating and Corporate Governance Committee considers a wide range of factors, including directors' experience, knowledge, integrity, understanding of our business environment and specific skills they may possess that are helpful to the Company (including leadership experience, financial expertise and industry knowledge). The committee seeks to balance the experience, skills and characteristics represented on the Board and does not assign specific weight to any of these factors. In addition, the committee generally believes it is important for all Board members to possess the highest personal and professional ethics, integrity and values, an inquisitive and objective perspective, a sense for priorities and balance, the ability and willingness to devote sufficient time and attention to Board matters, and a willingness to represent the long-term interests of all our stockholders.

*Board Diversity*

The Nominating and Corporate Governance Committee actively seeks to achieve a diversity of occupational and personal backgrounds on the Board, including with respect to gender, race, ethnicity, national background, geography, sexual orientation and age. The Nominating and Corporate Governance Committee assesses its effectiveness in balancing these considerations in connection with its annual evaluation of the composition of the Board. In this regard, our current Board of nine directors has three directors who self-identify as female (33%) and one director who self-identifies as racially/ethnically diverse (11%).

In accordance with Nasdaq's board diversity listing standards, we are disclosing aggregated statistical information about our Board's self-identified gender and racial characteristics and LGBTQ+ status as voluntarily confirmed to us by each of our directors.

**Board Diversity Matrix**
(as of the date of this Proxy Statement)

| | Female | Male | Non-Binary | Did Not Disclose Gender |
|---|---|---|---|---|
| **Total number of directors: 9** | 3 | 5 | — | 1 |
| **Number of directors who identify in any of the categories below:** | | | | |
| African American or Black | — | — | — | — |
| Alaskan Native or Native American | — | — | — | — |
| Asian | — | — | — | — |
| Hispanic or Latinx | — | — | — | — |
| Native Hawaiian or Pacific Islander | — | — | — | — |
| White | 2 | 4 | — | — |
| Two or More Races or Ethnicities | — | 1 | — | — |
| LGBTQ+ | | | — | |
| Did Not Disclose Demographic Background | | | 2 | |

*Stockholder Recommendations for Directors*

It is the Nominating and Corporate Governance Committee's policy to consider written recommendations from stockholders for director candidates. The committee considers candidates recommended by our stockholders in the same manner as a candidate recommended by other sources. Any such recommendations should be submitted to the committee as described under "Stockholder Communications" and should include the same information required under our bylaws for nominating a director, as described under "Stockholder Proposals and Director Nominations for Next Year's Annual Meeting."

## Board Leadership Structure

Dr. Golumbeski serves as our independent Chairman while Dr. Schreiber serves as our Chief Executive Officer. Our Principles of Corporate Governance provide our Board with the flexibility to combine or separate the positions of Chairman and CEO. Currently, the Board believes that the roles of Chairman and CEO should be separate and that the Chairman should be an independent director as this structure enables our independent Chairman to oversee corporate governance matters and our CEO to focus on leading the Company's business. At any time when there is not an independent Chairman, the Board will designate one or more independent directors to serve as lead director.

The independent directors have the opportunity to meet in executive sessions without management present at every regular Board meeting and at such other times as may be determined by the Chairman. The purpose of these executive sessions is to encourage and enhance communication among independent directors.

The Board believes that its programs for overseeing risk, as described under "Board Risk Oversight," would be effective under a variety of leadership frameworks. Accordingly, the Board's risk oversight function did not significantly impact its selection of the current leadership structure.

## Director Independence

Nasdaq listing rules require a majority of a listed company's board of directors to be comprised of independent directors who, in the opinion of the board of directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Subject to specified exceptions, each member of a listed company's audit, compensation and nominating committees must be independent, and audit and compensation committee members must satisfy additional independence criteria under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our Board undertook a review of its composition and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, our Board has determined that each of our current directors listed above under "Information Regarding Director Nominees and Continuing Directors," with the exception of Dr. Schreiber, is an "independent director" as defined under the Nasdaq listing rules. Dr. Schreiber is not an independent director because he is our Chief Executive Officer. In making such determinations, our Board considered the relationships that each such non-employee director has with the Company and all other facts and circumstances our Board deemed relevant in determining independence, including the Company's ordinary course business relationship with Tempus AI (pursuant to which Tempus AI and an affiliate provides certain contract research services to the Company) where Dr. Sasser serves as Chief Scientific Officer, but does not oversee, and has no material involvement with or material interest in, the services rendered to the Company, and the payments to Tempus AI, which represent an insignificant portion of its revenues. Our Board also determined that each of the directors currently serving on the Audit Committee and the Compensation Committee satisfy the additional independence criteria applicable to directors on such committee under Nasdaq listing rules and the rules and regulations established by the SEC.

**Board Committees**

Our Board has a separately designated Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, each of which is comprised solely of independent directors with the membership and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees is empowered to retain outside advisors as it deems appropriate, regularly reports its activities to the full Board and has a written charter, which is posted on our website located at *ir.shattucklabs.com*, under "Governance."

| Name | Audit Committee | Compensation Committee | Nominating and Corporate Governance Committee |
|---|---|---|---|
| Taylor Schreiber, M.D., Ph.D. | | | |
| Helen M. Boudreau | Chair | X | |
| Tyler Brous | X | Chair | |
| Carrie Brownstein, M.D. | | | X |
| Neil Gibson, Ph.D. | X | | Chair |
| George Golumbeski, Ph.D. | | X | |
| Michael Lee | | | X |
| Kate Sasser, Ph.D. | | | |
| Clay Siegall, Ph.D. | | | |
| # of Meetings in 2023 | 6 | 6 | 3 |

***Audit Committee.*** The primary responsibilities of our Audit Committee are to oversee the accounting and financial reporting processes of the Company, including the audits of the Company's financial statements, the integrity of the financial statements and the annual review of the performance, effectiveness and independence of the outside auditor. This includes reviewing the financial information provided to stockholders and others and the adequacy and effectiveness of the Company's internal controls. The committee also makes recommendations to the Board as to whether financial statements should be included in the Company's Annual Report on Form 10-K.

Ms. Boudreau qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

***Compensation Committee.*** The primary responsibilities of our Compensation Committee are to periodically review and approve the compensation and other benefits for our senior officers and directors. This includes

reviewing and approving corporate goals and objectives relevant to the compensation of our senior officers, evaluating the performance of these officers in light of those goals and objectives, and setting the officers' compensation based on those evaluations. The committee also administers and makes recommendations to the Board regarding equity incentive plans that are subject to the Board's approval and approves the grant of equity awards under the plans.

The Compensation Committee may delegate its authority to one or more subcommittees. The committee may also delegate authority to review and approve the compensation of our employees to certain of our executive officers. Even where the committee does not delegate authority, our executive officers will typically make recommendations to the committee regarding compensation to be paid to our employees and the size of equity awards under our equity incentive plans, but will not be present during voting or deliberations on their own compensation. The committee has the authority to engage outside advisors, such as compensation consultants, to assist it in carrying out its responsibilities. The Compensation Committee engaged Aon in 2023 to provide advice regarding the amount and form of executive and director compensation. The committee has determined that (1) Aon satisfies applicable independence criteria, and (2) Aon's work with the Company does not raise any conflicts of interest, in each case under applicable Nasdaq listing rules and the rules and regulations established by the SEC.

***Nominating and Corporate Governance Committee.*** The primary responsibilities of our Nominating and Corporate Governance Committee are to engage in succession planning for the Board, develop and recommend to the Board criteria for identifying and evaluating qualified director candidates, and make recommendations to the Board regarding candidates for election or reelection to the Board at each annual stockholders' meeting. In addition, the committee is responsible for overseeing our corporate governance practices and making recommendations to the Board concerning corporate governance matters. The committee is also responsible for making recommendations to the Board concerning the structure, composition and functioning of the Board and its committees.

## Board Risk Oversight

We believe that risk management is an important part of establishing and executing on the Company's business strategy. Our Board, as a whole and at the committee level, focuses its oversight on the most significant risks facing the Company and on the Company's processes to identify, prioritize, assess, manage and mitigate those risks. The committees oversee specific risks within their purview, as follows:

- **The Audit Committee** has overall responsibility for overseeing the Company's practices with respect to risk assessment and management. Additionally, the committee is responsible for overseeing management of risks related to our accounting and financial reporting processes, and information technology and cybersecurity.
- **The Compensation Committee** is responsible for overseeing management of risks related to our compensation policies and programs.
- **The Nominating and Corporate Governance Committee** is responsible for overseeing management of risks related to director succession planning and our corporate governance practices.

Our Board and its committees receive regular reports from members of the Company's senior management on areas of material risk to the Company, including strategic, operational, financial, legal and regulatory risks. While our Board has an oversight role, management is principally tasked with direct responsibility for assessing and managing risks, including implementing processes and controls to mitigate their effects on the Company.

## Other Corporate Governance Practices and Policies

### *Director Attendance*

The Board met six times during the year ended December 31, 2023. During 2023, each director then-serving on the Board attended at least 75% of the aggregate number of meetings of the Board and the committees on

which he or she served during the period in which he or she was on the Board or committee. Directors are encouraged to attend the annual meeting of stockholders. Six of our directors then-serving on the Board attended the 2023 Annual Meeting of Stockholders.

### *Stockholder Communications*

Stockholders and other interested parties may communicate with our Board or a particular director by sending a letter addressed to the Board or a particular director to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. These communications will be compiled and reviewed by our Corporate Secretary, who will determine whether the communication is appropriate for presentation to the Board or the particular director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

To enable the Company to speak with a single voice, as a general matter, senior management serves as the primary spokesperson for the Company and is responsible for communicating with various constituencies, including stockholders, on behalf of the Company. Directors may participate in discussions with stockholders and other constituencies on issues where Board-level involvement is appropriate. In addition, the Board is kept informed by senior management of the Company's stockholder engagement efforts.

### *Code of Conduct*

Our Board has adopted a Code of Business Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets and how to report compliance concerns.

A copy of the code is available on our website located at *ir.shattucklabs.com*, under "Governance." We intend to disclose future amendments to certain provisions of the code, and waivers of the code granted to our executive officers and directors, on our website to the extent required by applicable rules. Our Board is responsible for applying and interpreting the code in situations where questions are presented to it.

### *Anti-Hedging Policy*

We have a policy that prohibits our employees, officers, directors and consultants from engaging in, with respect to Company securities: (a) short-term trading; (b) short sales; (c) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (d) hedging transactions.

### *Compensation Committee Interlocks*

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

## Director Compensation

### *Non-Employee Director Compensation Policy*

We adopted a policy for compensating our non-employee directors with a combination of cash and equity. Our Compensation Committee, in consultation with Aon, its independent compensation consultant, periodically

reviews non-employee director compensation and recommends changes based on competitive market data. Most recently, changes to our non-employe director compensation policy, as described below, became effective on May 5, 2023 and were implemented in order to better align director compensation with that of our peer group. During 2023, each director who was not an employee was entitled to receive cash compensation as set forth below (all such amounts paid in quarterly installments):

| Annual Cash Retainers | Amount ($) |
|---|---|
| Board membership (other than the Chairman or Lead Director) | 40,000 |
| Chairman of the Board | 70,000* |
| Lead Independent Director (if applicable) | 60,000 |
| *Additional annual retainers* | |
| Chair of the Audit Committee | 15,000 |
| Chair of the Compensation Committee | 10,000 |
| Chair of the Nominating and Corporate Governance Committee | 8,000 |
| Member of the Audit Committee | 7,500 |
| Member of the Compensation Committee | 5,000 |
| Member of the Nominating and Corporate Governance Committee | 4,000 |

* Such amount was $65,000 prior to May 2023.

In addition to the annual retainers, during 2023, each of our non-employee directors was eligible for equity awards consisting of, as applicable: (i) an initial, one-time award of stock options, restricted stock or restricted stock units, as determined in the discretion of the Compensation Committee, to each new non-employee director upon his or her election to the Board, with a grant date fair value equal to $250,000 that vests over a three-year period, subject to such director's continued service; and (ii) an annual award of 40,258 stock options that vests on the first anniversary of the date of grant (or if sooner, immediately prior to the Company's next annual meeting of stockholders). Prior to May 2023, our non-employee director compensation policy provided that the annual award be granted in the form of stock options, restricted stock or restricted stock units, as determined in the discretion of the Compensation Committee, with a grant date fair value equal to $125,000.

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

We reimburse all necessary and reasonable out-of-pocket expenses incurred by non-employee directors in connection with their service on our Board, subject to any applicable Company policies that may be in effect from time to time.

Our Board periodically reviews our director compensation program and may revise the compensation arrangements for our directors from time to time.

***Fiscal Year 2023 Non-Employee Director Compensation Table***

The following table shows the compensation earned in 2023 by the non-employee directors who served on the Board during such year. Dr. Schreiber did not receive any additional compensation for his 2023 Board service. For additional information on Dr. Schreiber's 2023 compensation, see the "Executive Compensation" section below.

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($)[1] | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|
| Helen M. Boudreau | 60,000 | 80,955 | — | 140,955 |
| Tyler Brous | 57,500 | 80,955 | — | 138,455 |
| Carrie Brownstein, M.D. | 44,000 | 80,955 | — | 124,955 |
| Neil Gibson, Ph.D. | 55,500 | 80,955 | — | 136,455 |
| George Golumbeski, Ph.D. | 73,242 | 80,955 | — | 154,197 |
| Michael Lee[2] | 44,000 | 80,955 | — | 124,955 |

(1) Amounts shown in this column represent the aggregate grant date fair value of stock options granted during the year ended December 31, 2023, as computed in accordance with FASB Accounting Standards Codification Topic 718. On May 26, 2023, each non-employee director serving at such time was granted an annual equity award in the form of an option covering 40,258 shares with a per share exercise price of $2.72. The assumptions used in calculating the grant date fair value of the awards reported in the Option Awards column are described in Note 10, Stock-Based Compensation and Employee Benefit Plans, to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2023. Note that the amounts reported in this column reflect the aggregate accounting cost for these awards, and do not necessarily correspond to the actual economic value that may be received by the director from the awards.

(2) Mr. Lee serves as Managing Director of Redmile Group, LLC ("Redmile"). Pursuant to the policies of Redmile, the compensation Mr. Lee receives for his service on our Board is remitted to Redmile.

As of December 31, 2023, each of the company's non-employee directors held the following aggregate number of option awards:

| Name | Option Awards |
|---|---|
| Helen M. Boudreau | 168,806 |
| Tyler Brous | 112,636 |
| Carrie Brownstein, M.D. | 90,983 |
| Neil Gibson, Ph.D. | 143,461 |
| George Golumbeski, Ph.D. | 213,331 |
| Michael Lee[1] | 85,236 |

(1) Pursuant to the policies of Redmile, Mr. Lee holds the stock options as a nominee on behalf, and for the sole benefit, of Redmile and has assigned all economic, pecuniary and voting rights in respect of the stock options to Redmile. Mr. Lee disclaims beneficial ownership of these options.

## EXECUTIVE OFFICERS

Biographical and other information regarding our executive officers is set forth below. There are no family relationships among any of our directors or executive officers.

| Name | Age (as of April 23, 2024) | Position |
|---|---|---|
| Taylor Schreiber, M.D., Ph.D.[1] | 44 | Chief Executive Officer and Director |
| Abhinav Shukla, Ph.D. | 51 | Chief Technical Officer |
| Arunthathy Nirmalini (Lini) Pandite, M.B.Ch.B. | 65 | Chief Medical Officer |
| Casi DeYoung | 53 | Chief Business Officer |
| Andrew R. Neill | 38 | Chief Financial Officer |
| Stephen Stout, Ph.D. | 49 | General Counsel, Corporate Secretary and Chief Ethics and Compliance Officer |

(1) For Dr. Schreiber's biographical information, see "Information Regarding Director Nominees and Continuing Directors" above.

***Abhinav Shukla, Ph.D.*** Dr. Shukla has served as our Chief Technical Officer since June 2021. Prior to joining the Company, from March 2020 to June 2021, Dr. Shukla served as the Chief Technical Operations Officer of Redpin Therapeutics, a gene therapy company, where he was responsible for all aspects of process, analytical and formulation development, and cGMP manufacturing. Previously, he held several senior leadership positions, including Vice President of Manufacturing at CRISPR Therapeutics AG (Nasdaq: CRSP), a biotechnology company, from April 2019 to November 2019, and Vice President and Head of Biologics Process Development at Shire plc, a biopharmaceutical company, from June 2018 to April 2019. Dr. Shukla served in several roles at KBI Biopharma Inc., a contract development and manufacturing company, from November 2011 to June 2018, including as Senior Vice President of Process Development and Manufacturing, where he helped build the foundation for their contract process development and manufacturing business. He served in a senior role helping to commercialize multiple biologic therapies at Bristol-Myers Squibb (NYSE: BMY), a pharmaceutical company, from 2006 to 2011 and in a senior technical role at Amgen Inc. (Nasdaq: AMGN), a biopharmaceutical company, from 2000 to 2006. Dr. Shukla received his undergraduate degree from the Indian Institute of Technology, Delhi and his Ph.D. in Chemical and Biochemical Engineering from Rensselaer Polytechnic Institute.

***Arunthathy Nirmalini (Lini) Pandite, M.B.Ch.B.*** Dr. Pandite has served as our Chief Medical Officer since July 2017. From May 2015 to June 2017, Dr. Pandite served as Head of Global Clinical Development and Senior Vice President at Adaptimmune Therapeutics plc (Nasdaq: ADAP), a clinical-stage biopharmaceutical company, where she was responsible for clinical development of the company's immuno-oncology pipeline. From May 2001 to April 2015, Dr. Pandite served in a number of roles at GlaxoSmithKline plc (NYSE: GSK), including as Vice President, Medicines Development Leader, and Head Unit Physician for Oncology. Dr. Pandite was an attending physician at Sylvester Comprehensive Cancer Center/Jackson Memorial Hospital in Miami from January 1998 to November 2000 and at Dana Farber Cancer Institute in Boston from July 1993 to August 1996, and has held academic appointments at Harvard University and the University of Miami. She served on the board of Codiak BioSciences, Inc. (Nasdaq: CDAK) from August 2021 to July 2023. She earned her M.B.Ch.B. from the University of Liverpool, England and her M.B.A. from Duke University.

***Casi DeYoung.*** Ms. DeYoung has served as our Chief Business Officer since December 2019. From June 2018 to December 2019, Ms. DeYoung served as Vice President and Chief Operating Officer for ImmuneSensor Therapeutics, an immunotherapy-focused biotechnology company, where she was responsible for corporate strategy, start-up operations, intellectual property, oversight of the company's first IND filing and the initiation of a first-in-human Phase I clinical trial. She served as Chief Business Officer at Mirna Therapeutics, Inc., an

oncology-focused biopharmaceutical company, from March 2014 to June 2017, Vice President of Business Development at Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company, from May 2008 to December 2013, Vice President of Business Development at ODC Therapy, Inc., a cancer immunotherapy company, from November 2005 to March 2008, and in various roles at EMD Pharmaceuticals, Inc., a subsidiary of Merck KGaA, and Merck KGaA (OTCMKTS: MKKGY) from 2000 to 2005. Ms. DeYoung earned her B.S. in Chemistry from Southwestern University and her M.B.A. from the McCombs School of Business at the University of Texas at Austin.

***Andrew R. Neill.*** Mr. Neill has served as our Chief Financial Officer since March 2021. He previously served as our Vice President of Finance and Corporate Development from July 2020 to March 2021 and as our Vice President of Corporate Development and Strategy from May 2017 to July 2020. From August 2010 to August 2016, Mr. Neill was the co-founder of Lumos Pharma, Inc. (Nasdaq: LUMO), a biopharmaceutical company focused on developing therapeutics for genetic rare diseases. From March 2009 to February 2014, Mr. Neill served as an analyst at Innovations in Drug Development, LLC, a pharmaceutical and biotechnology research management consulting company. Mr. Neill earned his B.B.A. from Texas Christian University and his M.B.A. with majors in Health Care Management and Finance from The Wharton School at the University of Pennsylvania, where he was a Kaiser Fellow.

***Stephen Stout, Ph.D.*** Mr. Stout has served as our General Counsel, Corporate Secretary and Chief Ethics and Compliance Officer since May 2023. He previously served as our Vice President of Intellectual Property from January 2022 through April 2023, and as our Intellectual Property Counsel from April 2021 through December 2021. Prior to that, Mr. Stout served as Special Counsel at Baker Botts L.L.P., a law firm, from October 2019 to March 2021 and in various roles at Vinson & Elkins LLP, a law firm, from October 2007 to October 2019, including as Partner from January 2016 to October 2019. During his time in private practice, he focused on federal litigation, particularly in intellectual property and technology disputes involving life sciences and digital media. He served on the board of directors for Volunteer Legal Services of Central Texas, a non-profit organization that provides legal services to low-income clients, from 2018 to 2022. Mr. Stout earned his J.D., with honors, from the University of Texas School of Law, his Ph.D. from the University of Texas at Austin, his M.S. from Louisiana State University and his B.S. from Texas A&M University. He is admitted to practice law in Texas and before the U.S. Patent & Trademark Office.

## EXECUTIVE COMPENSATION

Our named executive officers ("NEOs") for 2023, which consist of our principal executive officer and the next two most highly-compensated executive officers who served during the year ended December 31, 2023, are:

- Dr. Taylor Schreiber, our Chief Executive Officer;
- Dr. Arunthathy Nirmalini (Lini) Pandite, our Chief Medical Officer; and
- Mr. Andrew R. Neill, our Chief Financial Officer.

### 2023 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by or paid to our NEOs for 2023 and 2022.

| Name and Principal Position | Year | Salary ($) | Stock Awards[1] ($) | Option Awards[1] ($) | Non-Equity Incentive Plan Compensation[2] ($) | All Other Compensation[3] ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Taylor Schreiber, M.D., Ph.D. | 2023 | 525,000 | — | 241,523 | 262,500 | 5,385 | 1,034,408 |
| *Chief Executive Officer* | 2022 | 525,000 | — | 680,591 | 249,375 | 10,245 | 1,465,211 |
| Arunthathy Nirmalini (Lini) Pandite, M.B.Ch.B. | 2023 | 479,000 | 135,214 | 182,857 | 191,600 | 24,643 | 1,013,314 |
| *Chief Medical Officer* | 2022 | 479,000 | 258,103 | 362,583 | 182,020 | 18,514 | 1,300,220 |
| Andrew R. Neill | 2023 | 430,000 | 124,682 | 183,119 | 172,000 | 1,956 | 911,757 |
| *Chief Financial Officer* | | | | | | | |

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with FASB Accounting Standards Codification Topic 718) of equity awards granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 10, Stock-Based Compensation and Employee Benefit Plans, to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2023. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award is exercised and retention of the award through the applicable vesting period.

(2) Following the end of the fiscal year, we awarded each of our NEOs bonuses in respect of our performance in the prior fiscal year based on the achievement of individual and Company performance goals.

(3) Represents the sum of the Company's 401(k) plan matching contributions and life and AD&D insurance premiums paid on behalf of each of our NEOs.

**Outstanding Equity Awards at 2023 Fiscal-Year End Table**

The following table sets forth information regarding outstanding equity awards as of December 31, 2023 for each of our NEOs.

| | | Option Awards[1] | | | | | Stock Awards[2] | |
|---|---|---|---|---|---|---|---|---|
| Name | Grant Date | Number of Securities Underlying Unexercised Options Exercisable (#) | Number of Securities Underlying Unexercised Options Unexercisable (#) | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($) |
| Taylor Schreiber, M.D., Ph.D. . . . . | 8/6/2020 | 145,198 | 31,399 | — | 4.67 | 8/6/2030 | — | — |
| | 12/22/2020 | 20,672 | 6,891 | — | 53.02 | 12/22/2030 | — | — |
| | 1/10/2022 | — | — | 178,150 | 7.43 | 1/10/2032 | — | — |
| | 1/25/2023 | — | — | 165,050 | 3.57 | 1/25/2033 | | |
| Arunthathy Nirmalini (Lini) Pandite, M.B.Ch.B. . . . . | 9/19/2018 | 63,705 | — | — | 2.95 | 9/19/2028 | — | — |
| | 8/6/2020 | 68,504 | 13,696 | — | 4.67 | 8/6/2030 | — | — |
| | 12/22/2020 | 20,672 | 6,891 | — | 53.02 | 12/22/2030 | — | — |
| | 1/10/2022 | 33,290 | 36,185 | — | 7.43 | 1/10/2032 | — | — |
| | 1/10/2022 | — | — | — | — | — | 26,053 | 185,758 |
| | 1/25/2023 | — | 69,750 | — | 3.57 | 1/25/2033 | — | — |
| | 1/25/2023 | — | — | — | — | — | 37,875 | 270,049 |
| Andrew R. Neill . . . . | 9/19/2018 | 43,705 | — | — | 2.95 | 9/19/2028 | — | — |
| | 12/04/2019 | 68,500 | — | — | 3.17 | 12/04/2029 | — | — |
| | 8/06/2020 | 17,130 | 3,420 | — | 4.67 | 8/06/2030 | — | — |
| | 12/22/2020 | 10,956 | 3,652 | — | 53.02 | 12/22/2030 | — | — |
| | 1/10/2022 | 31,936 | 34,714 | | 7.43 | 1/10/2032 | — | — |
| | 1/10/2022 | — | — | — | — | — | 24,993 | 178,200 |
| | 1/25/2023 | — | 69,850 | — | 3.57 | 1/25/2033 | — | — |
| | 1/25/2023 | — | — | — | — | — | 34,925 | 249,015 |

(1) Each option award expires on the tenth anniversary of the date of grant. Except with respect to Dr. Schreiber's January 10, 2022 and January 25, 2023 stock option awards, 25% of each stock option award vests on the one-year anniversary of the grant date (or the vesting commencement date specified in the award agreement for 2020 grants) and the remainder of the shares underlying the options vest in equal installments over the next 36 months, subject to the applicable NEO's continued service through each such vesting date. Dr. Schreiber's January 2022 stock option award will only vest upon the Company's common stock achieving a price per share of at least $18.00 for 30 consecutive trading days. Dr. Schreiber's January 2023 stock option award was eligible to vest in three equal tranches upon the Company's common stock achieving a price per share of $4.00, $5.00 and $6.00 for 30 consecutive trading days, which occurred in January 2024.

(2) Each restricted stock unit award vests in four equal installments on each anniversary of the grant date, subject to the applicable NEO's continued service through each such vesting date. All Company equity awards currently outstanding, including stock options held by our NEOs, that were granted prior to the completion of our initial public offering ("IPO") in October 2020 were granted under the Shattuck Labs, Inc. 2016 Stock Incentive Plan. Such plan was discontinued in connection with the IPO and outstanding awards thereunder were cancelled and replaced with equivalent awards under the Shattuck Labs, Inc. 2020

Equity Incentive Plan (the "2020 Plan"). All equity awards granted following October 2020 were granted under the 2020 Plan.

**Employment Agreements**

***Dr. Schreiber.*** We are party to an employment agreement with Dr. Schreiber effective as of December 5, 2019. On March 27, 2020, Dr. Schreiber's employment agreement was amended to reflect his transition to serve as our Chief Executive Officer as of January 29, 2020, and this agreement was further amended on March 12, 2021. The agreement provides for his base salary, eligibility to receive an annual performance bonus with a target bonus amount of 30% of his base salary and eligibility to participate in the Company's employee benefit plans. The agreement provides for employment on an at-will basis and thus either party may terminate at any time for any or no reason, subject to 30 days' notice for Dr. Schreiber and the severance provisions described below in the section titled "Post-Employment Compensation and Change in Control Payments and Benefits." Dr. Schreiber's base salary was increased to $560,000 effective as of January 1, 2024 with a target bonus amount of 50%.

***Dr. Pandite.*** We are party to an employment agreement with Dr. Pandite effective as of December 5, 2019, pursuant to which she serves as our Chief Medical Officer. This agreement was amended on March 12, 2021. The agreement provides for her base salary, eligibility to receive an annual performance bonus with a target bonus amount of 35% of base salary and eligibility to participate in the Company's employee benefit plans. The agreement provides for employment on an at-will basis and thus either party may terminate at any time for any or no reason, subject to 30 days' notice for Dr. Pandite and the severance provisions described below in the section titled "Post-Employment Compensation and Change in Control Payments and Benefits." Dr. Pandite's base salary was increased to $498,000 effective as of January 1, 2024 with a target bonus amount of 40%.

***Mr. Neill.*** We are party to an employment agreement with Mr. Neill effective as of December 5, 2019. This agreement was amended on March 12, 2021. The agreement provides for his base salary, eligibility to receive an annual performance bonus with a target bonus amount of 40% of his base salary and eligibility to participate in the Company's employee benefit plans. The agreement provides for employment on an at-will basis and thus either party may terminate at any time for any or no reason, subject to 30 days' notice for Mr. Neill and the severance provisions described below in the section titled "Post-Employment Compensation and Change in Control Payments and Benefits." Mr. Neill's base salary was increased to $458,000 effective as of January 1, 2024, with a target bonus amount of 40%.

**2023 Annual Bonus Program**

At the beginning of 2023, the Compensation Committee established overall corporate performance goals and a methodology by which employees, including each of our NEOs, would be awarded an annual bonus based on achievement of the corporate performance goals. In addition, the Compensation Committee established that each of our NEOs would be eligible for bonus awards of up to the following target bonus amounts: Dr. Schreiber-$262,500, Dr. Pandite-$191,600 and Mr. Neill-$172,000. The corporate performance goals included key milestones with respect to the clinical development of SL-172154, continued research and development activities related to certain pre-clinical compounds, improvement of the Company's manufacturing processes and other corporate and business development objectives. Personal responsibility for achievement of, and individual performance in support of, the enumerated corporate goals was also evaluated by the Compensation Committee in assessing final performance for the year. Following its assessment of the level of achievement of the corporate goals in December 2023, the Compensation Committee approved final bonus payments to the NEOs based on achievement of corporate performance goals at 100% of target and the evaluation of each NEO's individual performance as follows: Dr. Schreiber-$262,500, Dr. Pandite-$191,600 and Mr. Neill-$172,000. Such bonus payments were made in February 2024.

**2023 Annual Equity Awards**

In January 2023, we awarded each of our NEOs annual equity awards in the form of restricted stock units and stock options, except for Dr. Schreiber who received only stock options. See the 2023 Summary Compensation Table and Outstanding Equity Awards at 2023 Fiscal-Year End Table for further information with respect to these awards.

**Post-Employment Compensation and Change in Control Payments and Benefits**

***Employment Agreements***

Pursuant to the terms of the employment agreements with each of the NEOs, upon a termination without cause or resignation with good reason not in connection with a change in control, the NEO will receive, subject to the NEO's execution and non-revocation of a release of claims in favor of the company, or the Release Condition, and continued compliance with restrictive covenants: (i) severance payments equal to one times the NEO's annual base salary, (ii) any earned but unpaid prior year annual bonus and a pro-rata annual bonus for the year of termination based on actual performance, (iii) accelerated vesting of all unvested equity awards granted on or prior to December 1, 2020 (with performance-based awards earned at the target level of performance) and (iv) payment of COBRA premiums for up to 12 months, or, if sooner, until eligible for similar coverage through another employer. If the NEO is terminated without cause or resigns for good reason within 30 days prior to, or 12 months following, a change in control, then the NEO severance multiplier will be increased from one to 1.5 and will apply to both the executive's annual base salary and target annual bonus, all outstanding equity awards will fully accelerate regardless of grant date, and the maximum COBRA premium payment period will be extended from 12 to 18 months. Severance payments remain subject to the Release Condition and compliance with restricted covenants.

"Good Reason" under each of the NEO employment agreements generally means the occurrence of any of the following events, without the executive's consent, provided, in each case, that such event is not cured within 30 days after the company receives notice from the executive specifying in reasonable detail the event constituting Good Reason: (i) failure to pay the annual base salary or annual bonus when due, (ii) a reduction in the annual base salary or annual bonus, (iii) any diminution in the executive's title or any substantial and sustained diminution in the executive's duties or (iv) a required relocation of the executive's primary work location by more than 25 miles.

"Cause" under each of the NEO employment agreements generally means: (i) indictment for, conviction of, or a plea of *nolo contendere* to, (x) a felony (other than traffic-related) under the laws of the United States or any state thereof or any similar criminal act in a jurisdiction outside the United States or (y) a crime involving moral turpitude that could be injurious to the company or its reputation, (ii) willful malfeasance or willful misconduct which is materially and demonstrably injurious to the Company, (iii) any act of fraud in the performance of executive's duties or (iv) a material breach of any agreement with the Company or any of the Company's material policies.

"Change in Control" under each of the NEO employment agreements generally means the occurrence of one or more of the following events: (i) any "person" (as such term is used in Sections 3(a)(9) and 13(d) of the Exchange Act) or "group" (as such term is used in Section 13(d)(3) of the Exchange Act), other than the company or its subsidiaries or any benefit plan of the company or its subsidiaries is or becomes a "beneficial owner" (as such term is used in Rule 13d-3 promulgated under the Exchange Act) of more than 50% of the voting stock of the Company; (ii) the Company transfers all or substantially all of its assets (unless the stockholders of the Company immediately prior to such transaction beneficially own, directly or indirectly, in substantially the same proportion as they owned the voting stock of the Company, all of the voting stock or other ownership interests of the entity or entities, if any, that succeed to the business of the Company or the Company's ultimate parent company if the Company is a subsidiary of another corporation); or (iii) any merger, reorganization, consolidation or similar transaction unless, immediately after consummation of such transaction,

the stockholders of the Company immediately prior to the transaction hold, directly or indirectly, more than 50% of the voting stock of the Company or the Company's ultimate parent company if the Company is a subsidiary of another corporation.

Each employment agreement provides that, to the extent that any payments would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code (the "Code"), each executive will be entitled to receive either: (a) the full amount of payments and benefits in connection with their employment with the Company or (b) a portion of the payments and benefits having a value equal to $1 less than three times the NEO's "base amount" (as defined in Section 280G(b)(3)(A) of the Code), whichever results in the receipt of the greater amount on an after-tax basis.

**Other Benefits**

We offer our eligible full-time employees, including our NEOs, the opportunity to participate in our tax-qualified 401(k) plan. Employees can contribute 1% to 99% of their eligible earnings up to the Internal Revenue Service's annual limits on a before-tax basis. We provide a 100% match of the first 3% and 50% match of the following 2% of eligible compensation. The matches we provided to our NEOs in 2023 are reflected in the "All Other Compensation" column of the 2023 Summary Compensation Table above. The matching funds that we provide are 100% vested. We maintain an employee stock purchase plan in order to enable eligible employees to purchase shares of our common stock at a discount. We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans.

**Incentive Compensation Clawback Policy**

We have adopted a Rule 10D-1 Clawback Policy, which is intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive during the prior three fiscal years that exceeds the amount that the executive otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

## CERTAIN INFORMATION ABOUT OUR COMMON STOCK

### Security Ownership of Certain Beneficial Owners and Management

The following table presents information regarding beneficial ownership of our common stock as of April 1, 2024 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors and nominees;
- each of our NEOs; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after the date of this table. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned.

The percentage ownership information shown in the column titled "Shares Beneficially Owned – Percentage" in the table below is based on 47,519,219 shares of our common stock outstanding as of the date of this table (plus any shares that such person has the right to acquire within 60 days after the date of this table). Unless otherwise indicated, the address of each individual listed in this table is the Company's address set forth on the first page of this Proxy Statement.

| | Shares Beneficially Owned | |
|---|---|---|
| **Name of Beneficial Owner** | **Number** | **Percentage** |
| **Greater than 5% Holders** | | |
| Entities affiliated with FMR LLC (Fidelity)[1] | 7,071,174 | 14.9% |
| Entities affiliated with Redmile Group, LLC[2] | 5,705,150 | 12.0% |
| Josiah Hornblower[3] | 2,977,627 | 6.3% |
| Entities affiliated with Prosight Management, LP[4] | 2,782,797 | 5.9% |
| Entities affiliated with Adage Capital Partners, L.P.[5] | 2,577,705 | 5.4% |
| **Named Executive Officers, Directors and Nominees** | | |
| Taylor Schreiber, M.D., Ph.D.[6] | 2,981,218 | 6.2% |
| Helen M. Boudreau[7] | 168,806 | * |
| Tyler Brous[8] | 342,308 | * |
| Carrie Brownstein, M.D.[9] | 87,494 | * |
| Neil Gibson, Ph.D.[10] | 196,206 | * |
| George Golumbeski, Ph.D.[11] | 267,944 | * |
| Michael Lee[12] | 85,236 | * |
| Kate Sasser, Ph.D. | — | — |
| Clay Siegall, Ph.D. | — | — |
| Lini Pandite, M.B.Ch.B.[13] | 352,200 | * |
| Andrew R. Neill[14] | 280,199 | * |
| **All Executive Officers and Directors as a group (14 persons)[15]** | 5,219,537 | 10.5% |

* Represents beneficial ownership of less than one percent.

(1) Based on a Schedule 13G/A filed on February 9, 2024 filed by FMR LLC and Abigail P. Johnson, and consists of shares held by subsidiaries of FMR LLC. Ms. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Ms. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940 to form a controlling group with respect to FMR LLC. Consists of (i) 7,071,174 shares over which FMR holds sole voting and dispositive power, (ii) no shares over which Ms. Johnson holds sole voting power and (iii) 7,071,174 shares over which Ms. Johnson holds sole dispositive power. The business address of each person and entity listed above is 245 Summer Street, Boston, Massachusetts 02210.

(2) Based on a Schedule 13D/A filed on December 26, 2023 and consists of the following: (i) 583,995 shares held by Redmile Capital Fund, L.P., (ii) 829,744 shares held by Redmile Capital Offshore Master Fund, Ltd., (iii) 46,923 shares held by Redmile Capital Offshore Fund (ERISA), Ltd., (iv) 374,149 shares held by Redmile Capital Offshore II Master Fund, Ltd., (v) 374,546 shares held by Redmile Strategic Long Only Trading Sub, Ltd., (vi) 485,259 shares held by Redmile Strategic Trading Sub, Ltd., (vii) 2,178,738 shares held by Redmile Biopharma Investments II, L.P., (viii) 670,795 shares held by RedCo I, L.P., (ix) 75,765 shares held by Map 20 Segregated Portfolio, a segregated portfolio of LMA SPC (together, the "Redmile Funds") and (x) 85,236 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date held by Mr. Lee. Mr. Lee is a member of our Board and a Co-Founder and Managing Director of Redmile. The stock options were granted to Mr. Lee in connection with his service as a member of our Board. Pursuant to the policies of Redmile, Mr. Lee holds the stock options as a nominee on behalf, and for the sole benefit, of Redmile and has assigned all economic, pecuniary and voting rights in respect of the stock options to Redmile. Redmile is the investment manager/adviser to each of the Redmile Funds and, in such capacity, exercises sole voting and investment power over all of the shares held by the Redmile Funds and may be deemed to be the beneficial owner of these shares. Jeremy C. Green serves as the managing member of Redmile and also may be deemed to be the beneficial owner of these shares. Redmile and Mr. Green each disclaim beneficial ownership of these securities, except to the extent of its or his pecuniary interest in such shares, if any. Excludes: (i) 1,233,414 shares underlying a warrant held by Redmile Strategic Long Only Trading Sub, Ltd., (ii) 316,997 shares underlying a warrant held by Redmile Strategic Trading Sub, Ltd. and (iii) 1,550,412 shares underlying a warrant held by Redmile Biopharma Investments II, L.P., which exercise is subject to a beneficial ownership limitation of 9.99% of the shares of common stock issued and outstanding. The business address of each person and entity listed above is c/o Redmile Group, LLC, One Letterman Drive, Building D, Suite D3-300, San Francisco, California 94129.

(3) Based on a Schedule 13D/A filed on December 9, 2022, and consists of 85,774 shares held directly by Mr. Hornblower and 2,891,853 shares held by Hornblower Capital Holdings, LLC. Hornblower Capital Holdings, LLC is controlled by Mr. Hornblower, and he may be deemed to be the beneficial owner of those shares. The business address of Mr. Hornblower is 3317 Bowman Avenue, Austin, Texas 78703.

(4) Based on a Schedule 13G filed on January 2, 2024, and consists of (i) 244,554 shares held by Prosight Fund, LP ("Prosight Fund"), (ii) 726,079 shares held by Prosight Plus Fund, LP ("Prosight Plus Fund") and (iii) 1,812,164 shares held in certain separate managed accounts (the "Managed Accounts") and by W. Lawrence Hawkins. Prosight Management, LP ("Prosight Management") is the general partner and investment manager of, and may be deemed to indirectly beneficially own securities owned by, Prosight Fund and Prosight Plus Fund. Prosight Management is a sub-advisor for the Managed Accounts and may be deemed to indirectly beneficially own securities owned by the Managed Accounts. Prosight Partners, LLC ("Prosight Partners") is the general partner of, and may be deemed to beneficially own, securities beneficially owned by Prosight Management. Mr. Hawkins is the sole manager of, and may be deemed to beneficially own securities beneficially owned by, Prosight Partners. Prosight Fund disclaims beneficial ownership of the shares of common stock held by each of the Managed Accounts, Prosight Plus Fund and

Mr. Hawkins. Prosight Plus Fund disclaims beneficial ownership of the shares held by each of the Managed Accounts, Prosight Fund and Mr. Hawkins. Mr. Hawkins disclaims beneficial ownership of the shares held by each of the Managed Accounts, Prosight Fund and Prosight Plus Fund. The business address of each person and entity listed above is c/o Prosight Management, LP, 5956 Sherry Lane, Suite 1365, Dallas, Texas 75225.

(5) Based on a Schedule 13G filed on January 29, 2024, and consists of 2,577,705 shares held by Adage Capital Partners, L.P. ("ACP"). Adage Capital Partners GP, L.L.C. ("ACPGP") is the general partner of ACP and holds shared voting and investment power over the shares held by ACP. Adage Capital Management, L.P. ("ACM") is the investment manager of ACP and holds shared voting and investment power over the shares held by ACP. Each of Robert Atchinson and Phillip Gross is a managing member of Adage Capital Advisors, L.L.C., which is the managing member of ACPGP, and a managing member of Adage Capital Partners LLC, which is the general partner of ACM, and holds shared voting and investment power over the shares held by ACP. The business address of each person and entity listed above is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.

(6) Consists of (a) 2,610,750 shares held by Houghton Capital Holdings, LLC, which is controlled by Dr. Schreiber, (b) 17,052 shares held in Dr. Schreiber's name and (c) 353,416 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date. Excludes 178,150 shares underlying options that will vest upon the Company's common stock achieving certain specified share prices.

(7) Consists of 168,806 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(8) Consists of (a) 229,672 shares and (b) 112,636 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(9) Consists of 87,494 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(10) Consists of (a) 52,745 shares and (b) 143,461 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(11) Consists of (a) 54,613 shares and (b) 213,331 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(12) Mr. Lee holds 85,236 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date as a nominee on behalf, and for the sole benefit, of Redmile. The stock options were granted to Mr. Lee in connection with his service as a member of our Board. Pursuant to the policies of Redmile, Mr. Lee has assigned all economic, pecuniary and voting rights in respect of the stock options to Redmile. Mr. Lee disclaims beneficial ownership of these options, which are also reported as beneficially owned for Redmile.

(13) Consists of (a) 124,111 shares and (b) 228,089 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(14) Consists of (a) 74,091 shares and (b) 206,108 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(15) Consists of (a) 3,190,582 shares and (b) 2,028,955 shares underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table contains information about our equity compensation plans as of December 31, 2023. As of such date, we had outstanding awards under three equity compensation plans: our 2016 Stock Incentive Plan (the "2016 Plan"), our 2020 Plan and our 2020 Employee Stock Purchase Plan (the "2020 ESPP").

| Plan Category | Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights | Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights[1] | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))[2] |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders | 5,532,567 | $7.21 | 5,188,630 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 5,532,567 | $7.21 | 5,188,630 |

(1) The weighted-average exercise price does not take into account shares issuable upon vesting of outstanding restricted stock unit awards, which have no exercise price.

(2) Includes 3,983,756 shares available for grant under the 2020 Plan and 1,204,874 shares available for grant under the 2020 ESPP, including 7,286 shares subject to purchase during the purchase periods in effect as of December 31, 2023. Excludes 1,890,404 and 472,601 shares that were added to the 2020 Plan and the 2020 ESPP, respectively, on January 1, 2024 pursuant to the evergreen provisions thereunder that provide for automatic annual increases on January 1 of each year until January 1, 2030 equal to 4% and 1%, respectively, of our outstanding shares as of the preceding December 31 (or such lesser amounts as approved by the Board). As of December 31, 2023, there were no shares available for future grants under the 2016 Plan.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 1, 2022 or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeds $120,000; and
- any related person (including our directors, executive officers, beneficial owners of more than 5% of our common stock, and any members of their immediate family) had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled "Executive Compensation" or that were approved by our Compensation Committee.

Beneficial ownership of securities is determined in accordance with the rules of the SEC.

### Related Party Transactions

***Second Amended and Restated Investors' Rights Agreement***

We are party to a second amended and restated investors' rights agreement effective as of June 12, 2020 (the "IRA") with our stockholders who previously held our redeemable convertible preferred stock and certain other stockholders. The IRA provides these holders with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. These registration rights will terminate no later than five years after the completion of our IPO or, with respect to any particular holder, at such time that such holder can sell its shares, under Rule 144 under the Securities Act or otherwise, during any 90-day period without registration. The IRA was entered into prior to our adoption of the formal, written policy described below, but was approved by our Board.

***2023 Private Placement***

On December 21, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain entities affiliated with Redmile (the "Purchasers"), relating to the purchase of pre-funded warrants to purchase 3,100,823 shares of common stock at a purchase price of $6.4499 per pre-funded warrant, for aggregate gross proceeds of $19,999,998.30, before deducting offering expenses (the "Private Placement"). Mr. Lee, a director of the Company, serves as Managing Director of Redmile. In addition, Redmile is a holder of more than 5% of the Company's common stock.

Each pre-funded warrant may be exercised for one share of common stock, is immediately exercisable, does not expire and is subject to a beneficial ownership limitation of 9.99% post-exercise. As of December 31, 2023, no pre-funded warrants have been exercised, and 3,100,823 pre-funded warrants remain outstanding.

In connection with the foregoing, on December 21, 2023, the Company also entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company granted the Purchasers certain registration rights with respect to the shares of common stock issuable upon the exercise of the pre-funded warrants.

### Related Person Transaction Policy

We have adopted a written related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which (i) the amount involved exceeds or is expected to exceed $120,000, (ii) the Company or any of our subsidiaries is a participant and (iii) any related person (as defined above) has or will have a direct or indirect interest. Transactions involving compensation for services provided to

us as an employee or director, among other limited exceptions, are deemed to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances.

Under the policy, if a transaction has been identified as a related person transaction, our Audit Committee must review the material facts and either approve or disapprove of the entry into the transaction. If advance approval of the transaction is not feasible, then the transaction will be considered and, if the Audit Committee determines it to be appropriate, ratified at the next regularly scheduled meeting. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to avoid activities that create or give the appearance of a conflict of interest, and directors and executive officers must consult and seek prior approval of potential conflicts of interest from the Audit Committee. In considering related party transactions, our Audit Committee will take into account the relevant available facts and circumstances including, but not limited to:

- whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances; and
- the extent of the related person's interest in the transaction.

## OTHER MATTERS

### Stockholder Proposals and Director Nominations for Next Year's Annual Meeting

Pursuant to Rule 14a-8 of the Exchange Act, stockholders who wish to submit proposals for inclusion in the proxy statement for the 2025 Annual Meeting of Stockholders must send such proposals to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. Such proposals must be received by us as of the close of business (6:00 p.m. Eastern Time) on December 24, 2024 and must comply with Rule 14a-8 of the Exchange Act. The submission of a stockholder proposal does not guarantee that it will be included in the proxy statement.

As set forth in our bylaws, if a stockholder intends to make a nomination for director election or present a proposal for other business (other than pursuant to Rule 14a-8 of the Exchange Act) at the 2025 Annual Meeting of Stockholders, the stockholder's notice must be received by our Corporate Secretary at the address set forth on the first page of this Proxy Statement no earlier than the 120th day and no later than the 90th day before the anniversary of the last annual meeting; provided, however, that if the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, the stockholder's notice must be delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the date on which the first public announcement of the date of such annual meeting is made by the Company. Therefore, unless the 2025 Annual Meeting of Stockholders is more than 30 days before or more than 60 days after the anniversary of the Annual Meeting, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary no earlier than February 7, 2025 and no later than the close of business (6:00 p.m. Eastern Time) on March 9, 2025. Any such director nomination or stockholder proposal must be a proper matter for stockholder action and must comply with the terms and conditions set forth in our bylaws. If a stockholder fails to meet these deadlines and fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. In addition to satisfying the deadlines in the advance notice provisions of our bylaws, a stockholder who intends to solicit proxies in support of nominees submitted under these advance notice provisions for the 2025 Annual Meeting must provide the notice required under Rule 14a-19 of the Exchange Act to our Corporate Secretary in writing not later than the close of business (6:00 p.m. Eastern Time) on April 8, 2025. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

### Delivery of Documents to Stockholders Sharing an Address

A number of brokerage firms have adopted a procedure approved by the SEC called "householding." Under this procedure, certain stockholders who have the same address and do not participate in electronic delivery of proxy materials will receive only one copy of the proxy materials, including this Proxy Statement, the Notice and our Annual Report on Form 10-K for the year ended December 31, 2023, until such time as one or more of these stockholders notifies us that they wish to receive individual copies. This procedure helps to reduce duplicate mailings and save printing costs and postage fees, as well as natural resources. If you received a "householding" mailing this year and would like to have additional copies of the proxy materials mailed to you, please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call (512) 900-4690, and we will promptly deliver the proxy materials to you. Please contact your broker if you received multiple copies of the proxy materials and would prefer to receive a single copy in the future, or if you would like to opt out of "householding" for future mailings.

### Availability of Additional Information

We will provide, free of charge, a copy of our Annual Report on Form 10-K for the year ended December 31, 2023, including exhibits, on the written or oral request of any stockholder of the Company. Please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement or call the number above.