UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

Commission File Number: 001-39662

SQZ BIOTECHNOLOGIES COMPANY

(Exact name of Registrant as specified in its Charter)

Delaware	**46-2431115**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Arsenal Yards Blvd, Suite 210 Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 758-8672

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**SQZ**	**New York Stock Exchange**

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant computed by reference to the price of the registrant's common stock as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, (based on the last reported sale price on the New York Stock Exchange as of such date) was approximately $80.3 million

The number of shares of Registrant's common stock outstanding as of March 11, 2023 was 29,491,125.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the Registrant's 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the end of the Registrant's fiscal year ended December 31, 2022 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Annual Report, including without limitation statements regarding our plans to develop, manufacture and commercialize our product candidates, the timing or outcome of our ongoing or planned clinical trials for SQZ-AAC-HPV and SQZ-eAPC-HPV and any future product candidates, the clinical utility of our product candidates, the anticipated impact of the COVID-19 pandemic and general economic conditions on our business and operations, including manufacturing, research and development, clinical trials and employees, our cash needs and availability, the sufficiency of our cash and cash equivalents and our ability to raise additional capital to fund our operations, our plans to mitigate the risk that we are unable to continue as a going concern, and the plans and objectives of management for future operations, are forward-looking statements.

The forward-looking statements in this Annual Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, those described in the sections of this Annual Report entitled "Summary Risk Factors," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

SUMMARY RISK FACTORS

We are subject to numerous risks and uncertainties, including those further described below in the section entitled "Risk Factors" in this Annual Report on Form 10-K, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following considerations, among others, may offset our competitive strengths or have a negative effect on our business strategy, which could materially adversely affect our business, financial conditions, results of operations, future growth prospects, or cause a decline in the price of our common stock:

- we have a limited operating history and no history of commercializing cell therapy products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability;
- we have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future, and we have no products that have generated any commercial revenue and we may never achieve or maintain profitability;
- we may be unable to successfully execute or achieve the anticipated benefits of the strategic realignment we announced in November 2022 to prioritize our clinical stage product candidates;
- we will require significant additional funding in order to complete development of and obtain regulatory approval for our product candidates and commercialize our products, if approved, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts;
- substantial doubt exists about our ability to continue as a going concern, which may require us to revise our business plan and strategy, liquidate certain assets to delay, scale back or cease our operations and may materially and adversely affect the price per share of our common stock and may make it more difficult for us to obtain financing;
- adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could affect our operations and liquidity;
- the COVID-19 pandemic has impacted, and likely will continue to impact, our operations and clinical trial execution and may materially and adversely affect our business and financial results in the future;
- our business is highly dependent on the success of our product candidates, each of which will require significant additional preclinical and clinical testing before we can seek regulatory approval and potentially launch commercial sales; if our product candidates do not receive regulatory approval or are not successfully commercialized, or are significantly delayed in doing so, our business will be harmed;
- preclinical and clinical development are lengthy and uncertain, and our preclinical programs or development candidates may be delayed or terminated, or may never advance to the clinic or commercialization, any of which may affect our ability to obtain funding and may have a material adverse impact on our platforms or our business;
- our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all;
- we are subject to extensive and costly government regulation;
- enacted and future healthcare legislation and policies may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and could adversely affect our business;
- developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets;
- the Roche Agreement is important to our business, and if we or Roche fail to adequately perform under the Roche Agreement, or if we or Roche terminate the Roche Agreement, the development and commercialization of certain of our product candidates could be materially delayed and our business would be adversely affected;
- we rely on third parties for the manufacture of raw materials and product candidates for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties; this reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts;
- we do not have multiple sources of supply for some of the components used in our product candidates, nor long-term supply contracts, and certain of our suppliers are critical to our production; if we were to lose a critical supplier or are subject to extended supply delays, it could have a material adverse effect on our ability to complete the development of

our product candidates; if we obtain regulatory approval for our product candidates, we would need to expand the supply of components in order to commercialize them;

- if we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected; and
- if we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer.

Item 1. Business.

Overview

SQZ Biotechnologies is a clinical-stage biotechnology company focused on unlocking the full potential of cell therapies to benefit patients. The company was founded on the therapeutic potential of the Cell Squeeze® process, our proprietary technology which allows for rapid delivery of a variety of cargo into different cell types. We aim to create multiple cell therapies that drive the immune system to combat diseases.

In oncology, we are developing cell therapy platforms that are based on directing tumor antigen-specific immune activation via engineered antigen presentation. We believe that by engineering physiological antigen presentation signals in subsets of peripheral blood cells that act on immune priming pathways, we have the potential to develop cell therapies that are designed to be potent drivers of tumor-specific immunity, well-tolerated, administered without lymphodepleting, preconditioning or hospitalization, and produced in under 24 hours.

2022 Significant Developments

In 2022, we executed on several key areas of our pipeline. On January 24, 2022, we announced U.S. Food and Drug Administration, or FDA, allowance to proceed under our Investigational New Drug application, or IND, for SQZ-eAPC-HPV and began enrolling patients in our Phase 1/2 clinical trial for the treatment of HPV16+ advanced solid tumors. In December 2022, we presented interim safety, biomarker and clinical data from the monotherapy part of the study at the 2022 European Society for Medical Oncology Immuno-Oncology, or ESMO-IO, Congress.

First-Generation SQZ-PBMC-HPV

As of December 31, 2022, we had dosed 30 patients in our Phase 1 trial for our first-generation antigen presenting cells, or APC, candidate, SQZ-PBMC-HPV, in HPV16+ advanced solid tumors. We reported preliminary biomarker and safety results at the recommended Phase 2 dose, or RP2D, of 5 million cells per kilogram (double prime) for 10 monotherapy patients and 7 patients in combination with checkpoint inhibitors (3 patients in combination with atezolizumab, or atezo, and 4 patients in combination with ipilimumab, or ipi) at the 2022 ESMO-IO Congress. Key observations from the reported data include, as of a cutoff date of October 16, 2022 (n=17 patients):

- SQZ-PBMC-HPV increased density of CD8+ tumor infiltrating lymphocytes (TILs), as a monotherapy in one checkpoint refractory head-and-neck cancer patient, which suggests a possible pharmacodynamic response at the RP2D. In conjunction with the increases in MHCI (HLA-A) expression and reduction in HPV16 antigen E6/E7 transcript, this signature was consistent with an inflamed tumor microenvironment and antigen-specific tumor killing.
- Across all patients dosed at the RP2D—in monotherapy and in combination cohorts—there were no observed treatment-related Grade 3 or greater serious adverse events, and no patient met the dose limiting toxicity, or DLT, criteria.
- Autologous cell therapy manufacturing was demonstrated in under 24 hours for all RP2D patients, with multiple doses produced and product release time of approximately one week.

As of December 31, 2022, we decided to no longer enroll patients in the SQZ-PBMC-HPV trial as we transition to our second-generation SQZ® eAPC therapeutic candidate.

Second-Generation SQZ-eAPC-HPV

Our lead eAPC product candidate leverages the added capabilities and functionality of multiple antigen presentation and immunological signals achieved through multiplexed mRNA delivery to diverse immune cell types. In January 2022, we received allowance to proceed with clinical trials from the FDA under our IND for SQZ-eAPC-HPV, our eAPC candidate engineered with HPV16 antigens, a costimulatory signal and membrane bound cytokines.

We initiated the SQZ-eAPC-HPV trial, the COMMANDER-001 Phase ½ study, in patients with HPV16+ advanced solid tumors in the first half of 2022 and provided initial interim data for 4 evaluable patients in the lowest-dose monotherapy cohort at the 2022 ESMO-IO Congress. Key findings as of the cutoff date of November 25, 2022, include:

- Stable disease observed in 2 out of 4 evaluable patients in eAPC phase 1/2 trial including a pronounced pharmacodynamic response—ELISpot summary showed maximal increase of E7 antigen reactivity of more than 14-fold—in a patient with prolonged stable disease.
- Safety data were consistent across all doses, mostly low-grade related AEs and no evaluable patient met pre-specified DLT criteria.
- Autologous cell therapy manufacturing was demonstrated in under 24 hours for all patients, with multiple doses produced and product release time of approximately one week.

Peer-Reviewed Publications

During the year, we had several peer-reviewed manuscripts published in scientific journals. The publications contain detailed preclinical work from multiple programs performed by us and key collaborators. The published manuscripts are as follows:

- Preclinical Results for SQZ® APC Program:
  Booty, Matthew et al. "Microfluidic Squeezing Enables MHC Class I Antigen Presentation by Diverse Immune Cells to Elicit CD8+ T Cell Responses with Antitumor Activity." *Journal of Immunology*, January 2022, doi:10.4049/jimmunol.2100656
- Preclinical Results for SQZ® Tolerizing Antigen Carriers (TAC) Program*:*
  Raposo, Colin et al. "Engineered RBCs Encapsulating Antigen Induce Multi-Modal Antigen-Specific Tolerance and Protect Against Type 1 Diabetes." *Frontiers in Immunology*, April 2022, doi.org/10.3389/fimmu.2022.869669
- Preclinical Results for Cell Squeeze® Technology*:*
  Park, J.C. et al. "Cell Squeeze: driving more effective CD8 T-cell activation through cytosolic antigen delivery." *ESMO Immuno-Oncology and Technology*, July 2022, doi.org/10.1016/j.iotech.2022.100091
- Preclinical Results for SQZ® AAC Program*:*
  Blagovic, Katarina et al. "Engineered red blood cells (activating antigen carriers) drive potent T cell responses and tumor regression in mice." *Frontiers in Immunology*, October 2022, doi.org/10.3389/fimmu.2022.1015585

Strategic Prioritization and Restructuring

On November 30, 2022, our Board of Directors approved a strategic prioritization of our clinical portfolio to concentrate on the development of our second-generation enhanced Antigen Presenting Cells (eAPC) cell therapy program, focused on HPV16 positive recurrent, locally advanced, or metastatic solid tumors. In the fourth quarter of 2022, the eAPC-HPV program received Fast Track Designation from the FDA for the treatment of HPV16+ recurrent, locally advanced, or metastatic solid tumors with disease progression following prior lines of systemic therapy. The strategic prioritization is a result of two primary factors:

- transitioning from our first-generation SQZ® APCs, or SQZ-PBMC-HPV, to our second-generation therapeutic candidate SQZ® eAPCs—which leverages the APC program by adding a costimulatory factor and membrane-bound cytokines to potentially amplify the impact that eAPCs may have on HPV16+advanced solid tumors—which was generally well-tolerated in cohort one of the monotherapy dose-escalation; and
- pausing development of other clinical and preclinical programs across oncology, immune tolerance, and infectious disease to preserve capital.

At that time, we also announced that the Board of Directors had approved a workforce reduction of approximately 60% and that Armon Sharei, PhD, Chief Executive Officer at SQZ Biotechnologies, stepped down from his role as CEO and member of the Board of Directors, effective November 30, 2022. The Board appointed Howard Bernstein, MD, PhD, former Chief Scientific Officer, and current director, as Interim Chief Executive Officer. Additionally, Micah Zajic, Chief Financial Officer, stepped down from his role as CFO, effective December 31, 2022.

During the year ended December 31, 2022, the Company recorded $4.9 million of restructuring charges, including employee-related costs of $4.5 million and facility related costs of $0.4 million. We expect to pay the majority of the

remaining accrued restructuring charges of approximately $3.2 million in cash-related expenses in the first quarter of 2023 and the balance by the third quarter of 2023. The remaining restructuring charges estimates are subject to assumptions, and actual amounts may differ. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the restructuring.

We also have several paused clinical and preclinical programs across oncology, immune tolerance, and infectious disease, as well other areas and indications, that are available for strategic partnerships or collaboration.

We believe that we can leverage our foundational Cell Squeeze® technology and our associated manufacturing systems, processes and capabilities, to enable our current and future therapeutic product candidates and to potentially improve the speed and reliability of cell therapy manufacturing beyond current practices. During our Phase 1 clinical trials, we have demonstrated the ability to manufacture our APC and eAPC therapeutic candidates in under 24 hours, with product release time of approximately one week. Additionally, we continue to progress development of an automated, point-of-care manufacturing system that we believe has the potential to produce future therapeutic candidates with improved manufacturing efficiency and lower cost.

Recent Developments

At the time of the restructuring announcement, the SQZ-AAC-HPV trial had one patient in the lowest- dose cohort on study. On December 21, 2022, after two treatment cycles, the patient's CT scan showed reduction of the target lesion—a right hilar lymph node—from 16 millimeters (mm) at baseline to 10mm, or approximately 38% from baseline, which was consistent with a partial response by RECIST 1.1 criteria. A subsequent scan on February 2, 2023, after four treatment cycles, showed further reduction of the target lesion to 8mm, or 50% from baseline, which was consistent with a confirmed partial response by RECIST 1.1 criteria, as well as an unconfirmed complete response. In March 2023, after seven cycles of SQZ-AAC-HPV, a CT scan confirmed the complete response by RECIST 1.1 criteria. Biomarker analysis on this patient identified an inflamed tumor microenvironment that highly expressed MHC1 cells and an increase in CD8+ cell density was observed. In light of this response in the first patient dosed, we decided to continue to enroll patients in the SQZ-AAC-HPV clinical trial. The Company has completed the dose-limiting toxicity period for the lowest-dose cohort. Following review and recommendation by the Study Safety Committee, the Company is advancing SQZ-AAC-HPV-101 trial to the highest-dose cohort. The company anticipates initial clinical data from the highest-dose cohort in the fourth quarter of 2023.

The ENVOY-001 trial is a Phase 1 open-label trial of our AAC HPV therapy candidate, or SQZ-AAC-HPV, as a monotherapy and in combination with immune checkpoint inhibitors in HLA-A*02+ patients with HPV16+ recurrent, locally advanced or metastatic solid tumors.

Clinical-Stage Cell Therapy Candidates

We believe our oncology cell therapy approach, which utilizes our clinical-scale microfluidic Cell Squeeze® system for cytosolic delivery of diverse cell programming biomolecules, has the potential to confer several advantages, including:

- the potential to activate potent tumor-specific CD8+ T cell responses as encoded by the target antigen cargo;
- multiplexed engineering of combinations of costimulatory and membrane-bound cytokine molecules that are designed to enhance stimulation and expansion of effector cells at the immune synapse; and
- potential for rapid and reliable manufacturing of engineered peripheral blood cell products in under 24 hours.

We believe our cell therapy candidates have the potential for broad development spanning solid cancer types as a result of the different disease antigen cargo that can be squeezed into multiple cell types to drive targeted killing of tumor cells.

We are currently developing two therapeutic candidates with unique product characteristics and mechanistic benefits based on the principles of antigen-specific immune stimulation:

SQZ® Enhanced APC Platform: The eAPC platform has the potential to yield novel multi-engineered cell therapy candidates comprising antigenic, costimulatory and membrane-bound cytokine components. SQZ® eAPCs are designed to potentially augment the T cell activation signal and to elicit a polyclonal T cell response. In addition, eAPCs are engineered with mRNAs that encode full-length antigenic proteins, potentially eliminating existing HLA restrictions with the intent to substantially broaden the addressable patient population. Our first eAPC platform candidate, SQZ-eAPC-HPV, was developed by multiplexed engineering of PBMCs with five different mRNAs.

SQZ® Activating Antigen Carrier Platform: SQZ® AACs are derived from engineering red blood cells, or RBCs, with the Cell Squeeze® technology to comprise tumor-specific antigens and adjuvant. We published preclinical research on our AAC program in *Frontiers in Immunology* in October 2022. AACs are designed to take advantage of the natural physiological process of aged RBC clearance to target resident, professional APCs in lymphoid organs that can subsequently prime endogenous T cells to drive antitumor activity. We are currently enrolling patients in the Phase 1 ENVOY-001 trial for the SQZ-AAC-HPV investigational therapy in HPV16+ advanced or metastatic tumors.

Programs Available for Partnership or Collaboration

Autoimmune Diseases

SQZ Tolerizing Antigen Carrier Platform: In 2022, we completed a pre-IND meeting with the FDA and performed IND-enabling activities for SQZ® Tolerizing Antigen Carrier (TAC) platform with the aim to treat autoimmune diseases by inducing antigen-specific immune tolerance. We published preclinical research on our TAC program in *Frontiers in Immunology* in April 2022. Our research, to date, has been focused on Type 1 Diabetes and Celiac Disease. Our TACs are derived from engineering RBCs to comprise disease-specific antigens and are designed to leverage the natural physiological process of aged RBC clearance. SQZ® TACs have demonstrated the potential to induce multiple mechanisms of immune tolerance, including the deletion of disease-driving T cells, in preclinical mouse models.

Infectious Diseases

We believe our SQZ® APC, eAPC and AAC platforms have the potential to provide therapeutic benefit by driving antigen-specific immune responses in chronic and acute infectious disease settings. In preclinical studies, we have demonstrated the versatility of our eAPCs to elicit targeted CD8+ T cell activation for multiple well-known disease antigens, including in hepatitis B virus, or HBV, cytomegalovirus, or CMV, influenza A virus, or IAV, and simian immunodeficiency virus, or SIV. Chronic HBV represents a large patient population with significant unmet need, and clinical evidence suggests that the levels of virus-specific T cells are correlated with patient outcomes and disease control.

Company History

Our company is founded on the novel discovery of Cell Squeeze® technology. This foundational technology is based on the work of former Chief Executive Officer, Dr. Armon Sharei, in the laboratories of Dr. Klavs Jensen and Dr. Robert Langer at the Massachusetts Institute of Technology. In a series of experiments with a complex, high-pressure, fluid-jet delivery system, the team discovered that rapid mechanical deformation of cells enables intracellular delivery of biomaterials, resulting in the first prototype of the SQZ® microfluidic chip. Through collaboration with leading scientists in the immunology and regenerative medicine fields, the team discovered the process' novel capabilities and potential for significant impact through engineering of cell biology and function. SQZ Biotechnologies was founded with the goal of realizing the broad potential of this technology and developing cellular medicines that are effective and well-tolerated, with improved therapeutic accessibility, for patients around the world.

Our Strategy

Our vision is to build a fully integrated cell therapy company leveraging the Cell Squeeze® technology to develop differentiated, engineered cellular therapies. We plan to develop, and if approved, commercialize, cellular therapeutics from our directed immunity platform that can modulate targeted immune responses against cancer, and

potentially autoimmune and infectious diseases. To enable a future with impactful SQZ® cell therapy products as compelling early-line treatment options for patients, we are executing a strategy with the following key elements:

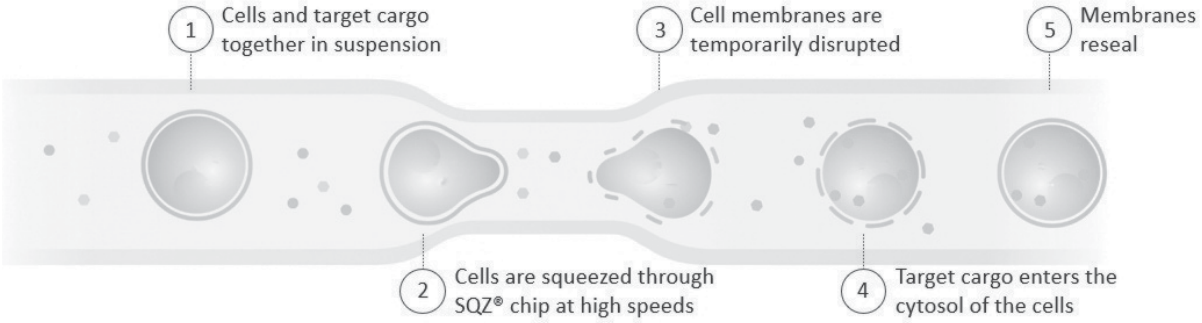
Advance HPV-specific cell therapy for the treatment of HPV-associated solid tumor malignancies. We believe that HPV+ cancers represent a promising lead application for our directed immunity platforms as the HPV16 viral oncogenes have been shown to be highly immunogenic and central to disease pathogenesis. Despite this, the mainstay first-line treatments do not differentially treat the underlying viral cause of HPV16+ tumors. Our strategy to target HPV16+ cancers is aimed at priming and activating T cell responses that can drive antitumor immunity. Our strategy is to develop our *ex vivo* engineered cell therapy candidates. The first is our SQZ-eAPC-HPV, or eAPC candidate, a multi-functional antigen presenting therapy with engineered immune activation signals, in monotherapy and potential combination treatment settings. The second our SQZ-AAC-HPV, or AAC candidate, is engineered to leverage the natural physiological process of aged RBC clearance to target resident, professional APCs that can subsequently prime endogenous T cells in effort to drive antitumor activity, in monotherapy and potential combination treatment settings.

We are currently enrolling patients in both programs with recurrent or metastatic HPV16+ cancers, including head-and-neck, cervical, and anal tumor types, in ongoing Phase 1 and Phase 1/2 trials. In current and future cohorts, we plan to evaluate our cell therapy candidates in combination with approved therapies as our preclinical studies indicate the potential for synergistic benefit with immune checkpoint inhibitors and/or chemotherapeutic agents. A combinatory approach could enable us to potentially reach a wider patient population at earlier lines of therapy, with the broader goal of improving standard of care treatment options for HPV16+ cancer patients.

- ***Through partnership or collaboration, we have the potential to broaden and deepen our pipeline by expanding to additional disease antigen targets within oncology as well as autoimmune and infectious disease areas.*** We may selectively pursue and form strategic partnerships or collaborations to capitalize on the broad potential of the Cell Squeeze® technology. We are encouraged by initial observations and progress in our ongoing Phase 1/2 clinical trial of SQZ-eAPC-HPV in HPV+ tumors and our ongoing Phase 1 clinical trial of SQZ-AAC-HPV-101 in HPV+ tumors, and, in the future, subject to capital availability, we plan to continue to advance the research and development of new product candidates directed against solid tumor, autoimmune and infectious disease targets with high unmet need. In preclinical studies, our directed immunity platforms focused on antigen-specific immune activation have demonstrated the potential to generate CD8+ T cell responses against multiple tumor antigens, including KRAS G12D and G12V epitopes, in addition to several infectious disease antigens associated with HBV, CMV, SIV and influenza. We believe the applicability of our therapeutic approach positions us to potentially pursue a wide range of antigenic targets across indication categories. We plan to leverage our core capabilities and expertise across antigen composition development and product optimization, our manufacturing system and processes, and our next-generation therapeutic platform advancements to further innovate and grow our future product portfolio. We have a longstanding collaboration with Roche for the development of SQZ® APCs in oncology, through a partnership that began in 2015 and which was subsequently expanded in 2018.
- ***Invest in our innovative manufacturing capabilities and advance our point-of-care system.*** We have developed proprietary manufacturing processes in compliance with applicable current good manufacturing practice, or cGMP, with our Cell Squeeze® platform, which we believe is a critical competitive advantage in the cell therapy field and a potential driver of our long-term success. We plan to continue investing resources to advance and innovate our existing manufacturing processes and systems with the goal of further reducing manufacturing time and cost, while upholding key product quality attributes. We are also developing an automated, point-of-care system that has shown the potential to streamline manufacturing time, labor, and logistics, enabling the potential for greater accessibility and patient impact of our cell therapy candidate. Our vision is to potentially generate patient doses for cell therapy candidates at or near specific treatment centers, thus significantly improving the patient experience. We have demonstrated initial engineering feasibility for engineered cells derived from PBMCs or RBCs on our point-of-care prototype.

SQZ® Technology

We have developed the Cell Squeeze® technology to be a rapid and versatile method of biomolecule delivery to cells and have demonstrated application of our clinical-scale Cell Squeeze® system to reliably yield patient dose production timelines of under 24 hours for our investigational SQZ-eAPC-HPV and SQZ-AAC-HPV therapeutic candidates. As illustrated below, the Cell Squeeze® approach utilizes microfluidic mechanical deformation which facilitates squeezing cells at high speeds through constriction(s) to temporarily disrupt the cell membrane and allow the target cargo to enter directly into the cytosol. At the current clinical scale, our proprietary system processes over 10 billion patient cells per minute.



We believe there are several advantages of utilizing the Cell Squeeze® technology as the manufacturing foundation of our cell therapy product candidates:

- **Translation across different cell types.** Our technology has demonstrated desired cytosolic delivery with over 25 mammalian cell types tested to date. We have created a library of SQZ® chips designed to perform with different cell populations that can be readily configured for use in our manufacturing systems. We believe this flexible configuration could help avoid costly cell expansion steps by potentially allowing us to leverage easier to access or manipulate cells. As a result, we believe this could enable us to potentially expand the breadth of indications we may consider for our cell therapy platform in the future.
- **Versatility across cargo materials.** Utilizing the Cell Squeeze® system, we have achieved intracellular delivery of peptides, proteins, small molecules, nucleic acids, and gene-editing complexes. Many of these material classes, such as proteins and peptides, are challenging to deliver with existing techniques. In addition, we can introduce multiple distinct materials into cells in a single squeeze run, allowing us to develop differentiated cell therapy candidates that include multiplexed engineering of different cellular functions, as leveraged in SQZ® eAPCs.
- **Preservation of cell health and function.** Evidence from our preclinical studies supports our belief that intracellular delivery with the Cell Squeeze® technology does not result in substantial transcriptomic, phenotypic, and functional alterations, which we believe could translate to cell therapy product candidates with the potential to offer improved manufacturability, activity, and viability. In the context of human T cells and hematopoietic stem cells in preclinical models, we observed minimal gene expression misregulation from squeezing relative to electroporation.
- **Scalability and operational practicality.** The underlying physical principles of intracellular delivery with the Cell Squeeze® technology have enabled us to design and adapt our systems and instrumentation to perform at clinical and potentially commercial scale, for the development of cell therapy product candidates. Our proprietary SQZ® chip, an integral component of the current Cell Squeeze® system, has demonstrated the ability to process up to 10 billion patient cells per minute. We believe that our manufacturing processes developed with current and future iterations of the Cell Squeeze® system support our ability to improve manufacturing efficiency and costs for our product candidates.

Our Differentiation

We believe our technologies, capabilities, and knowledge pertaining to the fields of cell engineering and immunology position us with the potential to create cell therapy candidates with differentiated and favorable product

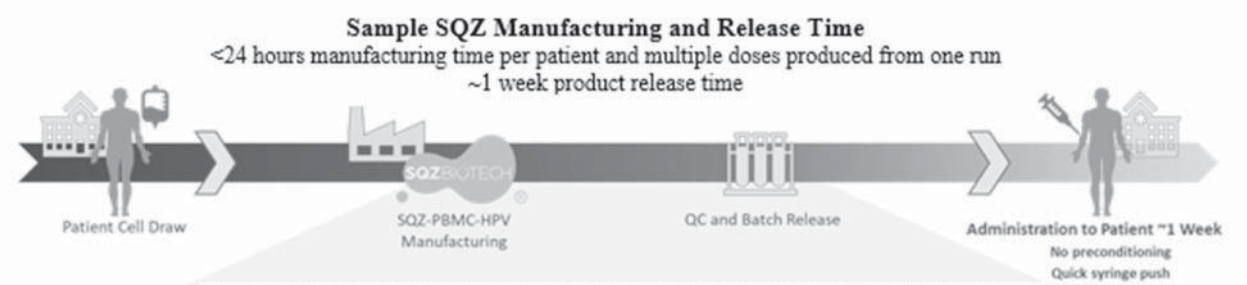
profiles for the treatment of cancer. We believe our cell therapy approach has the potential to offer meaningful benefits to patients and have broad therapeutic scope based on the following advantages:

- **Potential to immunologically target fundamental drivers of disease.** By engineering antigen presentation in a physiologically relevant manner, our therapeutic candidate is designed to generate immune responses that can potentially activate and expand endogenous T cells for the treatment of cancer. For example, the CD8+ T cell responses generated by our SQZ® eAPC platform has targeted specific tumor antigens, such as HPV E6 and E7 or KRAS mutants, to effectuate tumor regression in preclinical models. In addition, our directed immunity approach allows us to potentially access intracellular disease antigen targets to modulate immunity, which we believe is a key advantage to addressing tumor subsets and disease areas that are otherwise challenging to treat.
- **Integration of multiple functions in a single product candidate.** We have developed the technology advancements, expertise, and design approaches to engineer multiple cell types, including PBMCs and RBCs, with proprietary antigenic compositions and combinations of biomolecules to potentially enable diverse therapeutic functions. Our eAPC platform represents a next-generation cell therapeutic candidate in clinical testing, which involves multiplexed engineering of 5 different mRNAs into immune cells for the purposes of increasing the activation strength and durability of potential T cell responses against disease.
- **Potential for favorable safety and tolerability.** We believe that there are several distinguishing features to our therapeutic strategy and cell engineering approach that enable us to potentially create product candidates with the potential for favorable safety and tolerability outcomes. By acting on immune priming pathways to modulate endogenous effector cells, we believe we can circumvent the need for lymphodepleting conditioning which is commonly used in many current cell therapy treatment regimens and associated with significant toxicities to patients. Moreover, our current product candidate does not rely on genetic modifications to cells or treatment with viral vectors, potentially eliminating long-term safety concerns arising from unintended consequences to DNA disruption. We believe that this, coupled with our low cost-per-dose manufacturing, create the potential for the development of SQZ® therapeutic candidates into earlier lines of therapy.
- **Rapid, reliable, and flexible manufacturing of cell therapies.** We have demonstrated rapid clinical manufacturing in under 24 hours via our Cell Squeeze® clinical system for each of our investigational candidates. In addition, we believe that common elements of our established manufacturing processes enable us to potentially streamline future development timelines. We believe that eliminating the need for viral vectors and multi-day manufacturing could dramatically cut costs relative to current cell therapies and enable expansion into areas where current cell engineering approaches are cost prohibitive. We estimate manufacturing costs for SQZ-eAPC-HPV could be up to 10 times lower per dose at commercial scale compared to currently marketed cell therapies. In future iterations, our point-of-care system could potentially reduce costs even further.

Our Manufacturing

Since our founding, we have invested in and advanced our Cell Squeeze® platform, which includes our proprietary Cell Squeeze® technology, methods, and systems, with the aim to enable a variety of cell engineering applications for the development of cell therapy product candidates. We believe that the ability to manufacture cell therapies rapidly and reliably is an important competitive advantage in the cell therapy field, and we continue to innovate our manufacturing systems, processes, and capabilities with the intent to decrease the time, cost and complexity associated with cell therapy production.

With our current clinical-scale Cell Squeeze® system and associated manufacturing processes, we have demonstrated patient dose production times of under 24 hours and product release times of approximately one week for our therapeutic candidates. Our current manufacturing and release testing workflow is represented in the figure below.



Substantial improvement as standard methods commonly take over a month

Manufacture and Release	Standard	SQZ® Implemented
Manufacture	>2 weeks	<24 hrs
QC testing	4 weeks	5 days
Sterility testing	2 weeks	4 days
Mycoplasma testing	4 weeks	2 days
CoA issuance	4 weeks	6 days
QA batch record review	4 weeks	2 days
QA deviations close-out	4 weeks	5 days
Total Time for Manufacture and Release	~4 weeks	~1 week

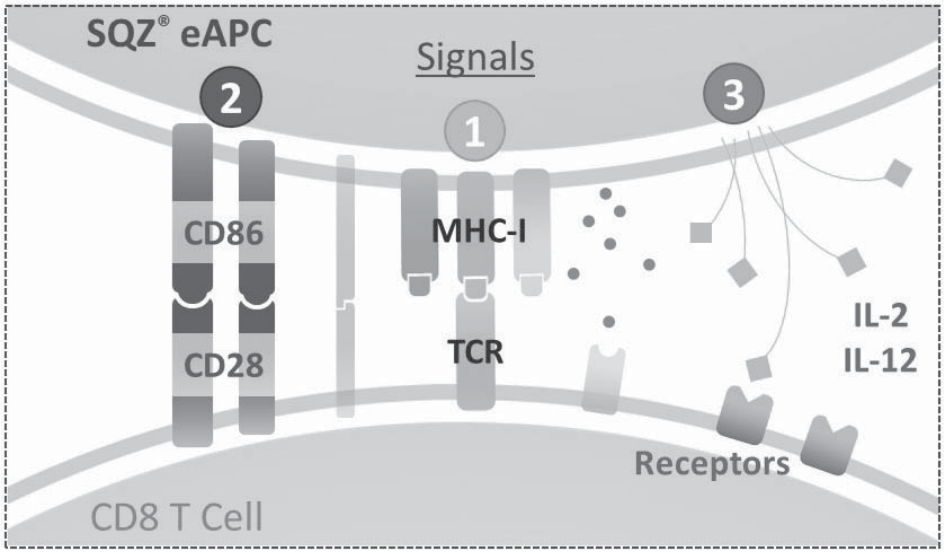
We have developed an automated, point-of-care manufacturing system that could potentially streamline manufacturing and future product candidate development timelines, furthering our broader vision to improve the accessibility and patient impact potential of cell therapies. In May 2022, we provided preclinical data showcasing the SQZ® point-of-care manufacturing system substantially reduced manufacturing times and operator hours, while preserving or improving on key product viability metrics when compared to our standard manufacturing practices. We believe there is potential to operate the point-of-care manufacturing system outside of a clean room which could further reduce manufacturing costs for our therapeutic product candidates.

Product Candidate Pipeline

SQZ® Enhanced Antigen Presenting Cell (eAPC) Platform

eAPC Platform Overview

The SQZ® eAPC platform is the second-generation product candidate designed to generate tumor-specific CD8+ T cell activation to drive the antitumor immune response. eAPCs utilize direct antigen presentation to engineer the three canonical T cell activation signals of peptide-MHC (Signal 1), costimulatory proteins (Signal 2) and cytokines (Signal 3), into the antigen presenting cells in an effort to create novel, multi-functional cell therapy product candidates for driving antitumor immunity. CD8+ T cells are known to be important effectors of the adaptive immune system, and are foundational to the recent clinical success of immunotherapy in oncologic indications.



SQZ® eAPCs are engineered from peripheral blood mononuclear cells (PBMCs) by using the Cell Squeeze® system to simultaneously deliver 5 mRNAs encoding for full length HPV16 E6 and E7 proteins, CD86, and membrane-bound (mb) IL-2 and mbIL-12 cytokines.

While there has been significant interest in therapeutic immunization approaches to prime CD8+ T cell responses in an antigen-specific manner, it has remained challenging to effectuate adequate responses for antitumor applications. We believe that our approach, utilizing Cell Squeeze® delivery, enables us to engineer antigen presentation in multiple peripheral blood cell types to create a cellular vaccine that has the potential to direct antigen-specific immunity.

To mount an immune response, CD8+ T cells require antigen presentation on major histocompatibility complex class I, or MHC-I, molecules by APCs. Antigenic peptides displayed on MHC-I are primarily sourced from the cytosol. Traditionally, antigen-targeted cell therapies and vaccine systems, which introduce antigens in the extracellular vicinity, have relied on a process called cross-presentation to route to the MHC-I pathway. Cross-presentation can generally be considered an ineffective mechanism of MHC-I presentation to CD8+ T cells, as typically only a fraction of introduced antigen material is present in the cytosol for MHC-I loading.

In contrast, in preclinical studies, our microfluidic Cell Squeeze® technology demonstrated abilities to deliver a variety of antigens directly into the cytosol, enabling potent antigen presentation for CD8+ T cell priming. In January 2022, we published peer-reviewed in vitro potency data for our first-generation SQZ® APCs (the predecessor to our eAPC platform) in the *Journal of Immunology*, where we demonstrated Cell Squeeze®-mediated cytosolic delivery yielded 1000-fold more efficient CD8+ activation relative to cross-presentation in dendritic cells.

Through accessing the MHC-I antigen presentation pathway in a physiological manner, we believe we can activate CD8-driven adaptive immunity against targeted diseases. Based on our preclinical research, we believe the SQZ® eAPC platform demonstrated the potential to achieve several coordinates of a T cell response.

SQZ® eAPCs is an autologous product candidate and is generated through the engineering of patient B cells, T cells, Natural killer, or NK, cells, and monocytes with 5 mRNAs encoding antigen-specific and immunological functions in a single Cell Squeeze® step. We believe that our eAPC platform has the potential to provide several therapeutic benefits, including:

- Presentation of a greater repertoire of antigenic epitopes (Signal 1) to CD8+ and CD4+ T cells, with the aim to remove existing human leukocyte antigen (HLA) restrictions and broaden immune recognition of tumor cells

- Expression of costimulatory molecules, such as CD86, that synergize with antigen presentation to promote T cell activation, expansion, and survival

- Expression of proprietary, membrane-bound versions of cytokines, such as IL-2 and IL-12, that can potentially augment T cell proliferation to effector phenotypes, while reducing the toxicity risks associated with systemic administration of cytokines

We believe that our approach to engineering PBMCs as eAPCs has the potential to represent an advancement over previous antigen-specific methods by augmenting the quantity, quality, and breadth of targeted T cell responses, and by integrating multiple immunological functions into a single therapeutic. We believe that eAPCs can have broad therapeutic potential across a range of solid cancers, and that we can utilize current and future generations of our cell therapy platform to target a variety of tumor antigens with the aim to drive antitumor immunity. In preclinical studies, we have demonstrated the potential of eAPCs to generate functional T cell responses across multiple antigen target categories, including virally derived antigens, such as HPV, that are known to be highly immunogenic and point mutants, such as KRAS G12D and G12V, that are considered less immunogenic.

SQZ® eAPC Product Candidate: SQZ-eAPC-HPV

HPV+ Cancers Incidence and Unmet Need

Human papillomavirus, or HPV, infection causes some of the most common types of cancer, such as cervical and head and neck cancer, and there is significant need for new treatment options to address HPV+ tumors. According to the Centers for Disease Control, or CDC, in the United States, HPV+ tumors represent 3% of all cancers in women and 2% of all cancers in men, resulting in over 36,000 new cases of HPV+ tumors every year. HPV+ tumors represent 4.5% of all cancers worldwide, according to the *International Journal of Cancer*, resulting in 570,000 new cases for women and 60,000 new cases for men globally every year. According to the CDC, HPV infection plays a significant role in the formation of more than 90% of anal and cervical cancers, and most cases of vaginal (75%), oropharyngeal (70%), vulval (70%) and penile (60%) cancers. In addition, an increasing percentage of head and neck cancer is being attributed to HPV infection, particularly those arising from the oropharynx.

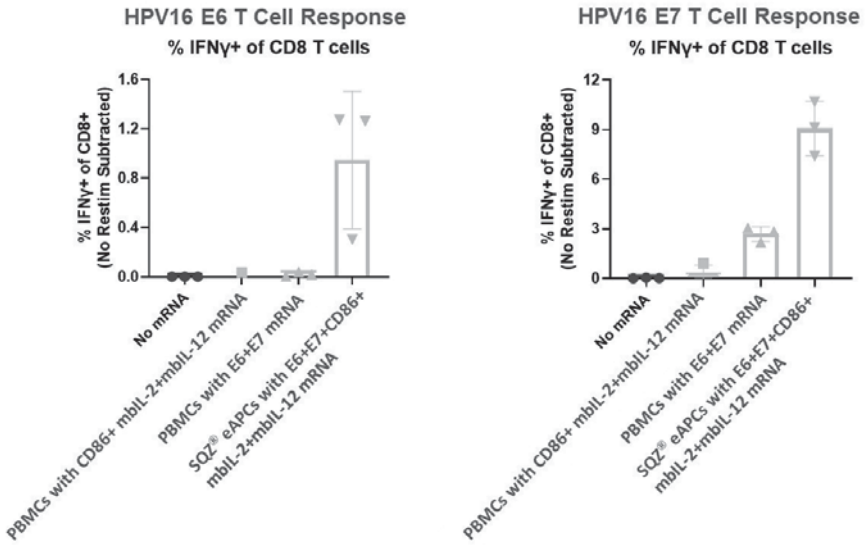
The standard first-line treatment for HPV+ cancers differs by tumor type but typically involves a combination of chemotherapy, radiation, surgery, and more recently, in certain HPV-associated tumor types, specific checkpoint inhibitors and molecular targeted therapies. However, in patients with recurrent, metastatic, or persistent disease, second-line treatment options are limited with deterioration in response rates and prognosis. For example, in recurrent or metastatic head and neck squamous cell carcinoma, or HNSCC, patients who have progressed during or after platinum-containing chemotherapy, the median overall survival is under 9 months.

Preclinical Development of SQZ-eAPC-HPV in Solid Tumors

Our lead eAPC product candidate, SQZ-eAPC-HPV, is engineered with mRNA cargo encoding the full-length HPV16+ E6 and E7 antigenic proteins and is in development for the treatment of HPV16+ tumors. Additionally, SQZ-eAPC-HPV is designed to express CD86 as a costimulatory molecule for T cell activation, as well as proprietary, membrane-bound versions of IL-2 and IL-12 (mbIL-2 and mb-IL-12) in an effort to further potentiate T cell activation and expansion. Our IND for a Phase 1/2 clinical trial to study SQZ-eAPC-HPV was allowed to proceed by the FDA in January 2022.

In November 2021, we presented preclinical data for SQZ-eAPC-HPV at the SITC Annual Meeting, where we demonstrated the following:

- SQZ-eAPC-HPV generated HPV16-specific CD8+ T cell responses, as measured by a substantial increase in stimulated CD8+ T cells relative to PBMCs with E6 and E7 mRNA and to PBMCs with CD86, mbIL-2 and mbIL-12 mRNA.



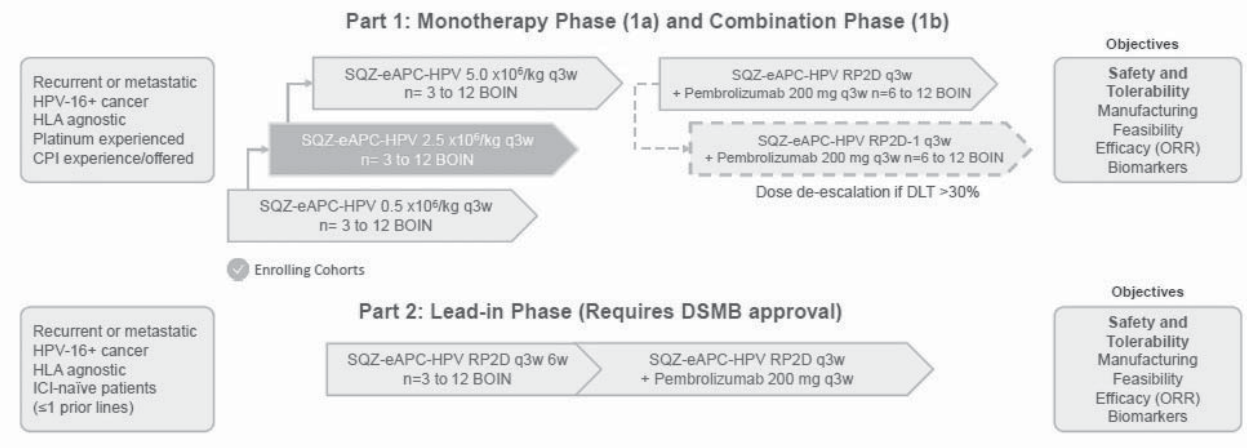
HPV16 E6 and E7 TCR-transduced CD8+ T cells were cultured for 6 days with autologous PBMCs that were squeezed in the presence of E6 and E7 mRNA and/or CD86, mbIL-2 and mbIL-12 mRNA. CD8+ T cells were restimulated with the E6 or E7 minimal epitopes, and intracellular cytokine staining for IFNγ was conducted to measure the expansion of HPV16-specific T cells.

Clinical Development of SQZ-eAPC-HPV in Solid Tumors

We are evaluating SQZ-eAPC-HPV in the Phase 1/2 COMMANDER-001 trial for recurrent, locally advanced, or metastatic HPV16+ solid tumors. The trial is an open-label, multicenter, dose escalation and expansion study to evaluate the safety and tolerability, immunogenic effects, antitumor activity, and pharmacodynamics of SQZ-eAPC-HPV as monotherapy and in combination with immune checkpoint inhibitors, including pembrolizumab. By not requiring any HLA inclusion criteria in the study, we expect to increase patient eligibility by approximately two- to three-fold.

The primary objectives of the trial are to evaluate safety and tolerability, as assessed by the number of participants with treatment-related adverse events and identify the RP2, of SQZ-eAPC-HPV monotherapy, which will be the dose utilized in combination with checkpoint inhibitors. The secondary objectives of the trial are evaluate antitumor activity in patients with recurrent, locally advanced, or metastatic solid tumors, based on tumor assessments using RECIST 1.1, and manufacturing feasibility, as assessed by individual patient batch yields. Initial safety data from the dose escalation / expansion trial were presented at the ESMO-IO annual congress in December 2022.

Study Design:



- Part1A: SQZ-eAPC-HPV monotherapy will be tested with at least 3 different dose levels to identify the RP2D.
- Part 1B: SQZ-eAPC-HPV RP2D will be tested in combination with 200mg pembrolizumab. Pembrolizumab will be given on cycle 1 day 8, then after SQZ-eAPC-HPV at every subsequent day 1.
- Part 2: SQZ-eAPC-HPV will be given as a monotherapy for the first 2 cycles (lead-in), then SQZ-eAPC-HPV and pembrolizumab are given in combination.

In December 2022, we presented initial interim results from the monotherapy dose escalation portion of the SQZ-eAPC-HPV trial in HPV16+ solid tumors at the ESMO-IO congress. Interim data were reported for four evaluable monotherapy patients in the lowest dose cohort—there was one patient in the second cohort that was not evaluable for the DLT. In an advanced population with a median of 3 prior lines of therapy. The interim results demonstrated that SQZ-eAPC-HPV was well-tolerated with stable disease as the best response. Key observations as of a cutoff date of November 25, 2022, include:

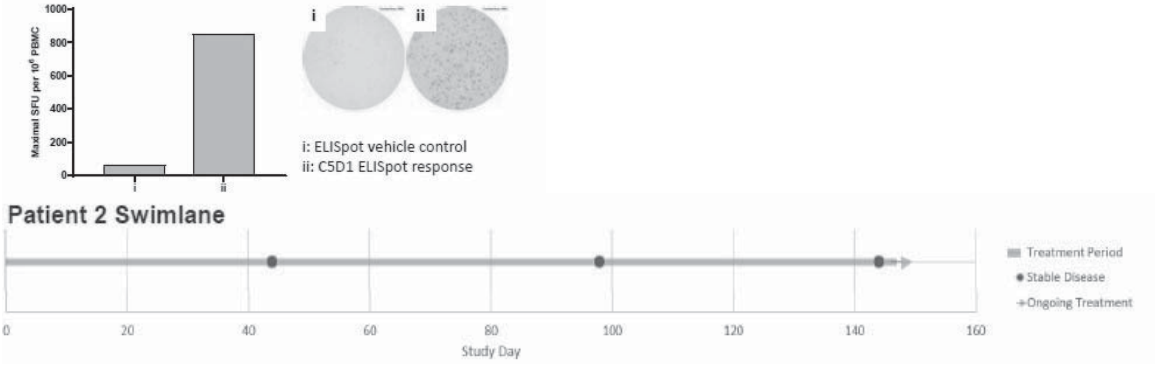
- Stable disease observed in 2 out of 4 evaluable patients in eAPC Phase 1/2 trial including a pronounced pharmacodynamic response in a patient with prolonged stable disease.
    - Positive ELISpot response in patient with stable disease
        - Samples were collected for testing in an IFNɣ ELISpot for E6 and E7 reactivity at every visit. Patient2 demonstrated the highest reactivity of any patient.
        - In patient 2, this E7 positive response correlated with persistent stable disease per RECIST1.1.

COMMANDER-001 Patient ELISpot Summary Data

	Patient	Maximum SFU per 10^6 PBMCs (above background)	Negative Cut-off value (SFU per 10^6 PBMCs)	Timepoint at maximal response	Best Overall Response per RECIST 1.1
Cohort 1	1	66	70	C3D1	Stable Disease
	2	848	60	C5D1	Stable Disease
	3	20	60	C1D8	Progressive Disease
	4	231	60	C2D8	Progressive Disease
Cohort 2	5	N/A	N/A	N/A	Not Evaluated

SFU = spot forming unit; IFNɣ ELISpot performed on non-expanded cells; minimal background detected

Efficacy and Preliminary Pharmacodynamic Data



- Safety results were consistent across all doses, mostly low-grade related AEs and no evaluable patient met pre-specified DLT criteria.

Safety Data & Tolerability Assessment Summary

	Cohort 1 (n=4)	Cohort 2 (n=1)	Total (N=5)
AE, Any Causality	3 (75.0)	1 (100.0)	4 (80.0)
AEs Occurring in >1 Patient, Any Causality			
Fatigue	2 (50.0)	1 (100.0)	3 (60.0)
Hypokalemia	2 (50.0)	0 (0.0)	2 (40.0)
Related AE	1 (25.0)	1 (100.0)	2 (40.0)
Fall	1 (25.0)	1 (0.0)	1 (20.0)
Hypertension	0 (0.0)	1 (100.0)	1 (20.0)
Related Grade 3+ AEs	0 (0.0)	1 (100.0)[1]	1 (20.0)
Related Serious AEs	0 (0.0)	0 (0.0)	0 (0.0)
AEs of Special Interest[2]	0 (0.0)	0 (0.0)	0 (0.0)
Dose-Limiting Toxicity	0 (0.0)	0 (0.0)	0 (0.0)
AEs leading to D/C	0 (0.0)	1 (100.0)[3]	1 (20.0)
Fatal Related AEs	0 (0.0)	0 (0.0)	0 (0.0)

[1]Grade 3 hypertension [2]AESIs are events suggestive of hypersensitivity [3]Grade 3 pneumonia

Cohort 1 was found to be generally well tolerated.

- Autologous cell therapy manufacturing was demonstrated in under 24 hours for all patients, with multiple doses produced and product release time of approximately one week.

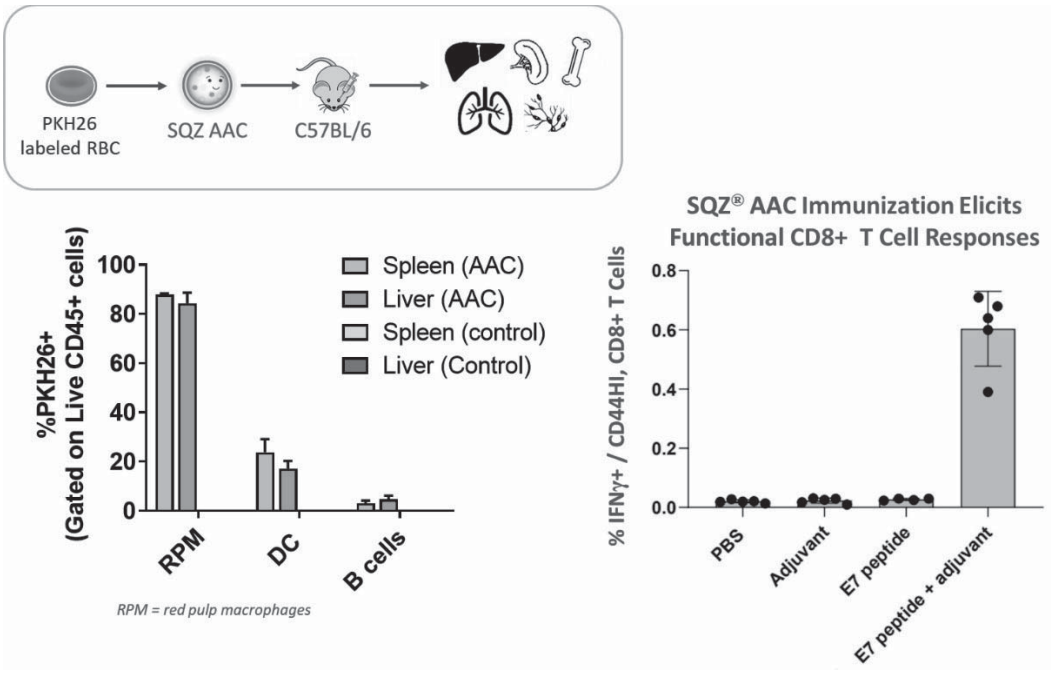
SQZ® Activating Antigen Carrier (AAC) Platform

AAC Platform Overview

The SQZ® AAC platform is designed to induce antigen presentation in vivo by deriving antigen carriers from engineering RBCs with tumor-specific antigens and adjuvant. We generated AACs by engineering red blood cells (RBCs) to encapsulate relevant tumor antigens and the adjuvant polyinosinic-polycytidylic acid (poly I:C) for use as a tumor-specific cancer vaccine. The processing method and conditions used to create the AACs are designed to promote phosphatidylserine exposure on RBCs and thus harness the natural process of aged RBC clearance to enable targeting of the AACs to endogenous professional antigen presenting cells (APCs). We believe our preclinical data support further development of AACs as a potential vector-free immunotherapy strategy to enable potent antigen presentation and T cell stimulation by endogenous APCs with broad therapeutic potential.

Preclinical Development of SQZ-AAC-HPV in Solid Tumors

To stimulate the adaptive immune system against specific antigens to yield CD8+ T cells with antitumor activity, we believe sufficient delivery of target antigens to APCs in an activating context is needed to enable MHC loading and T cell priming in lymphoid organs. While one arm of our directed immunity approach is based on ex vivo generation of APCs, the AAC arm focuses on leveraging the natural process of aged RBC clearance to target resident, professional APC populations in vivo to drive antigen-specific activation. In preclinical studies, we have shown that AACs were rapidly taken up by professional APCs, such as macrophages and dendritic cells, or DCs, in the spleen and liver, and that AACs loaded with target antigens and adjuvant subsequently drove antigen-specific CD8+ T cell responses. At the 2020 SITC Annual Meeting, we presented murine data on the in vivo pharmacokinetics and functional activity of SQZ® AAC therapeutic immunization, which we believe support the potential of AACs as a differentiated, directed immunity platform. In October 2022, we published our preclinical work in a peer-reviewed journal, *Frontiers in Immunology,* which showcases how AACs drove potent T Cell Responses and tumor regression in mice.



We believe that AAC product candidates could confer favorable attributes for a cellular therapy, including the potential for improved tolerability due to the physiological and targeted nature of immune activation, a more streamlined patient experience with whole blood collection without the need for leukapheresis and with administration via syringe push, and the potential for synergistic benefit with other immune-oncology and chemotherapeutic agents.

Clinical Development of SQZ-AAC-HPV in Solid Tumors

The ENVOY-001 trial is a Phase 1 open-label trial of our AAC HPV therapy candidate, or SQZ-AAC-HPV, as a monotherapy and in combination with immune checkpoint inhibitors in HLA-A*02+ patients with HPV16+ recurrent, locally advanced or metastatic solid tumors.

The first patient (Patient 1) in the lowest-dose cohort of the SQZ-AAC-HPV-101 trial is a 61-year-old male with a history of HPV16+ metastatic rectal squamous cell carcinoma. He had two prior lines of treatment but has not been treated with immune checkpoint inhibitors (ICI).

On December 21, 2022, after two treatment cycles, Patient 1's CT scan showed reduction of the target lesion—a right hilar lymph node—from 16 millimeters (mm) at baseline to 10mm, or approximately 38% from baseline, which was consistent with a partial response by RECIST 1.1 criteria. A subsequent scan on February 2, 2023, after four treatment cycles, showed further reduction of the target lesion to 8mm, or 50% from baseline, which was consistent with a confirmed partial response by RECIST 1.1 criteria, as well as an unconfirmed complete response. In March 2023, after seven cycles of SQZ-AAC-HPV, a CT scan confirmed the complete response by RECIST 1.1 criteria. Biomarker analysis on this patient identified an inflamed tumor microenvironment that highly expressed MHC1 cells and an increase in CD8+ cell density was observed. In light of this response in the first patient dosed, we decided to continue to enroll patients in the SQZ-AAC-HPV clinical trial. The company has completed the dose-limiting toxicity period for the lowest-dose cohort. Following review and recommendation by the Study Safety Committee, the Company is advancing SQZ-AAC-HPV-101 trial to the highest-dose cohort. The company anticipates initial clinical data from the highest-dose cohort in the fourth quarter of 2023.

Partnership or Collaboration Platforms

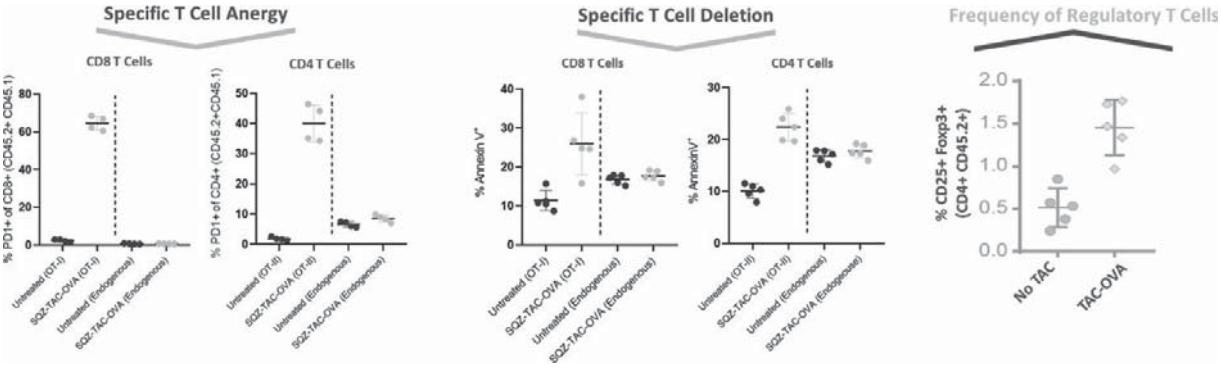
Autoimmune Diseases

SQZ® Tolerizing Antigen Carrier (TAC) Platform

TAC Platform Overview

Our SQZ® TAC platform is designed to induce antigen-specific immune tolerance in vivo by utilizing a similar approach to the AAC platform, whereby TACs are derived from engineering RBCs to modulate and suppress unwanted immune responses in a targeted manner.

As with our AAC platform, we utilize proprietary methods and processes for generating TACs, which induce changes associated with RBC senescence, to enable targeting to resident populations of professional APCs, such as macrophages, in lymphoid organs. SQZ® TACs are designed to take advantage of the naturally tolerogenic process of aged RBC clearance and are subsequently aimed to drive antigen-specific immune tolerance through multiple cellular mechanisms considered relevant to the pathology of complex autoimmune diseases. In preclinical studies with transgenic OT-I and OT-II murine models, we evaluated multi-modal mechanisms of tolerance induced by TAC treatment, including upregulation of markers of anergy associated with functional inactivation of CD8+ and CD4+ T cells, targeted deletion of antigen-specific T cells, and expansion of antigen-specific regulatory T cells, or Tregs. In April 2022, key preclinical data and results from our TAC platform studies were published in *Frontiers in Immunology:*



Adapted from Raposo et al. 2022. Frontiers in Immunology. doi:10.3389/fimmu.2022.869669

We believe that the potential of TACs to regulate both autoreactive CD4+ T cells and CD8+ T cells through multiple pathways may enable the development of differentiated therapeutic candidates for the treatment of diverse autoimmune diseases.

Infectious Diseases

Our Pipeline for Infectious Diseases

We believe that our cell therapy platforms aimed at antigen-specific immune activation have therapeutic potential across multiple infectious disease indications. Virus-specific CD8+ T cell activity has been shown to be associated with disease control and improved outcomes in certain diseases, such as chronic HBV, which could be a promising avenue for our directed immunity approach.

Collaboration, Research and License Agreements

Roche Collaboration

In October 2018, we entered into a License and Collaboration Agreement, or the Roche Collaboration Agreement, under which we are collaborating with Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd., or together, Roche, in the development and commercialization of certain nucleated cell therapy product candidates that incorporate antigens for the treatment of oncologic indications in accordance with mutually agreed upon collaboration plans. The Roche Collaboration Agreement enhanced, replaced and terminated a 2015 collaboration agreement between us and Roche.

We agreed, under the Roche Collaboration Agreement, to collaborate with Roche in the development of a cell therapy for oncologic indications made from PBMCs. The initial mutually selected antigen target is HPV, which is

the focus of our ongoing SQZ-PBMC-HPV Phase 1 clinical trial. We also agreed to use commercially reasonable efforts to mutually select additional antigens to develop collaboratively. For each mutually selected antigen (including HPV with respect to SQZ-PBMC-HPV), we are responsible for conducting all preclinical research, and all development activities occurring prior to achieving clinical proof of concept for a product candidate containing the antigen, generally through a Phase 1 clinical trial. With respect to each mutually selected antigen, we granted Roche an option, exercisable after we deliver to Roche a clinical proof-of-concept report for a product candidate containing the antigen, to obtain an exclusive license, under our intellectual property, to research, develop, make, use, import, sell, and otherwise exploit the product candidate worldwide for the treatment of oncologic indications using our SQZ platform and a microfluidic chip. We retain all rights with respect to any product for which Roche does not timely exercise its option, and we may elect to commercialize any such product independently. Following Roche's exercise of its option for a given product candidate, Roche is then responsible for the further clinical development of that product candidate, unless we exercise our option to exploit the product candidate in the United States, as further described below. Roche granted us an option, exercisable with respect to every alternating mutually selected antigen product for which Roche exercises its own option, beginning with the second, to retain the right under our intellectual property, and to obtain an exclusive license under Roche's intellectual property, to research, develop, make, use, import, sell and otherwise exploit the antigen product candidate in the United States. If we exercise our option, the parties will mutually determine how responsibility for clinical development will be allocated between them, but Roche has the final say as to which party will run each global clinical study. We own any invention relating solely to a product containing a mutually selected antigen that is developed prior to the exercise of Roche's option. If Roche exercises its option, Roche owns each subsequently developed invention relating solely to the antigen product candidate unless (a) it is solely related to the SQZ platform or microfluidic chips or is dominated by certain patents that belong to us and are necessary or useful for the practice of our SQZ platform or microfluidic chips, or (b) we exercise our option for the product candidate, in which case we will own such invention in the United States, and Roche will own such invention in all other jurisdictions. The budgeted development costs for these antigens are shared by the parties unless and until (i) Roche exercises its option with respect to a given antigen product candidate, and (ii) we do not exercise our option with respect to that antigen product candidate. In such case, Roche will be responsible for subsequent development costs.

Under the Roche Collaboration Agreement, if we propose an antigen that is not ultimately mutually selected for collaborative development, we may still pursue the development of product candidates containing that antigen. For each such antigen that we select, we may be responsible for conducting all preclinical research, and all development activities occurring prior to achieving a clinical proof of concept for an antigen product candidate containing the antigen. With respect to each such antigen product, Roche grants us an exclusive license under its intellectual property to research, develop, make, use, import, sell, and otherwise exploit the product in the United States. If we achieve a proof of concept for a product candidate containing such antigen, Roche will, for a limited period of time, have the option to obtain an exclusive license under our intellectual property to research, develop, make, use, import, sell, and otherwise exploit the product candidate worldwide (subject to our rights to exploit the product in the United States) for the treatment of oncologic indications using our SQZ platform and a microfluidic chip. We retain all rights with respect to any product candidate for which Roche does not timely exercise its option. Following Roche's exercise of its option, the parties will mutually determine how responsibility for clinical development will be allocated between them, but Roche has the final say as to which party will run each global clinical study. We own any invention relating solely to a product candidate containing an antigen we select that is developed prior to the exercise of Roche's option. If Roche exercises its option, we will own in the United States, and Roche will own in all other jurisdictions, each subsequently developed invention relating solely to the antigen product candidate, unless such invention is solely related to the SQZ platform or microfluidic chips or is dominated by certain patents that belong to us and are necessary or useful for the practice of our SQZ platform or microfluidic chips. We are responsible for all development costs for such antigen, unless and until Roche exercises its option, in which case the development costs subsequently incurred will be shared by the parties.

If Roche proposes an antigen and it is not ultimately mutually selected for collaborative development, Roche may elect to pursue the development of products containing that antigen. At Roche's cost, we are responsible for conducting all preclinical research, and all development activities occurring prior to achieving a clinical proof of concept for an antigen product candidate containing such antigen. Roche is responsible for all clinical development after a proof of concept is achieved. Roche owns any invention relating solely to antigen product candidates containing such antigen, unless the invention is solely related to the SQZ platform or microfluidic chips or is dominated by certain patents that belong to us and are necessary or useful for the practice of our SQZ platform or

microfluidic chips. Roche is responsible for all of the development costs for product candidates containing such antigens.

Under the Roche Collaboration Agreement, preliminary collaboration plans with defined preclinical goals exist for eAPC development and for product candidates containing tumor cell lysate, or TCL. We are responsible for conducting preclinical research and development activities occurring prior to achieving a clinical proof of concept for each such product. With respect to each TCL product candidate, we granted Roche an option, exercisable after we deliver to Roche a clinical proof-of-concept report for such TCL product candidate, to obtain an exclusive license, under our intellectual property, to research, develop, make, use, import, sell, and otherwise exploit the product candidate worldwide for the treatment of oncologic indications using our SQZ platform and a microfluidic chip. We retain all rights with respect to any product candidate for which Roche does not timely exercise its option. Following Roche's exercise of its option, Roche is then responsible for the further clinical development of each such product candidate. We own any invention relating solely to a TCL product candidate that is developed prior to the exercise of Roche's option. If Roche exercises its option, each subsequently developed invention relating solely to a TCL product candidate will be owned by Roche, unless it is solely related to the SQZ platform or microfluidic chips or is dominated by certain patents that belong to us and are necessary or useful for the practice of our SQZ platform or microfluidic chips. Prior to the exercise of Roche's option for a given tumor lysate product candidate, we will share the budgeted Phase 1 clinical costs of developing that product candidate, with Roche responsible for a mid double-digit percentage of the costs and SQZ responsible for the remainder. After Roche exercises its option, we may in some cases elect to opt out of sharing development costs; in such cases, Roche is thereafter responsible for all development costs incurred after exercising its option with respect to a given tumor lysate product candidate. If we do not timely elect to opt out of sharing development costs incurred after Roche's option exercise, the costs will be shared, with Roche responsible for a mid double-digit percentage and SQZ responsible for the remainder. We will share certain profits and losses associated with the commercialization of TCL product candidates in the United States with Roche, unless we opt out of the cost sharing. In the fourth quarter of 2022, we determined that based on our internal plans, which have not included work on TCL since 2019 and which do not anticipate performing work on TCL prior to the expiration of the option right, in addition to Roche's concurrence that no work was performed or expected to be performed in 2023, we could recognize the remaining deferred revenue of $9.2 million in the fourth quarter of 2022.

We own any invention developed under the Roche Collaboration Agreement that relates solely to the SQZ platform or microfluidic chips or is dominated by certain patents that belong to us and are necessary or useful for the practice of our SQZ platform or microfluidic chips. Any invention that does not relate solely to an antigen product candidate or TCL product candidate is owned by the party that invents it; if such invention is invented jointly, it is owned jointly by the parties. Each party may freely practice any jointly owned invention with no obligation to account to the other party.

Under the Roche Collaboration Agreement, Roche paid us an upfront payment of $45 million. We are eligible to receive aggregate milestone payments on a product-by-product basis of up to $1.6 billion upon the achievement of specified milestones, consisting of up to $217.0 million of development milestone payments, up to $240.0 million of regulatory milestone payments and up to $1.2 billion of sales milestone payments. Roche has agreed to pay us yearly tiered royalties based on net sales of antigen and TCL product candidates. For each antigen product candidate for which Roche commercializes outside of the United States, and we commercialize in the United States, Roche will pay us tiered royalties on net sales of the product candidate outside of the United States at rates ranging from a mid single-digit percentage to a mid-teens percentage, depending on net sales of the product candidate. For each such product, we will pay Roche tiered royalties on net sales of such product candidate in the United States at rates ranging from a mid single-digit percentage to a mid-teens percentage, depending on net sales of the product candidate in the United States. For antigen product candidates selected by Roche, rather than mutually, Roche will pay us tiered royalties on worldwide net sales of such product candidate at rates ranging from a mid single-digit percentage to a high single-digit percentage, depending on net sales of the product. For certain antigen product candidates with respect to which Roche commercializes worldwide, Roche will pay us tiered royalties at a rate ranging from a high single-digit percentage to a mid-teens percentage, depending on net sales of the product. No royalties will be due for SQZ antigens for which Roche does not exercise its option. For TCL product candidates, Roche will pay us tiered royalties on the aggregate net sales of all TCL products at rates ranging from either a mid single-digit percentage to a percentage in the low twenties, with the caveat that the rates for sales in the United States may instead range from a low teen percentage to a percentage in the mid twenties, depending on whether and

when we opt out of sharing certain profits and costs of commercializing the TCL product candidate in the United States with Roche.

Either party may terminate the Roche Collaboration Agreement (a) in its entirety or on a product-by-product or country-by-country basis if the other party breaches materially and such breach remains uncured for 90 days, or (b) in its entirety for insolvency-related events involving the other party. We may terminate the Roche Collaboration Agreement in its entirety or on a product-by-product or country-by country basis, if Roche or its affiliates or sublicensees commences an action challenging certain patent rights licensed to us and sublicensed to Roche. Roche may terminate the Roche Collaboration Agreement without cause (a) in its entirety or on a product-by-product basis with 60 days' notice, if Roche is terminating prior to exercising an option under the agreement, (b) on a product-by-product basis with 90 days' notice, if Roche is terminating after exercising an option under the agreement, (c) on a product-by-product basis or country-by-country basis with 180 days' notice if Roche is terminating after exercising an option under the agreement, and such notice will become effective on or after the first commercial sale of the product. For any product candidate that is terminated, we may provide a continuation election notice to Roche, and, for consideration, obtain from Roche all reasonably requested rights to such terminated product candidate, including the transfer of ownership of all INDs and regulatory approvals, and copies of data and reports relating to the product candidate, among other things.

MIT License Agreement

We exclusively license certain foundational technology from the Massachusetts Institute of Technology, or MIT, pursuant to an Amended and Restated Exclusive Patent License Agreement dated as of December 2, 2015, or the MIT License Agreement. The MIT License Agreement replaced an earlier Exclusive Patent License Agreement dated as of May 10, 2013, which was entered into in connection with the organization of the company. Under the MIT License Agreement, MIT granted us a worldwide, royalty bearing license to develop, make, have made, use, sell, offer to sell, lease, and import products incorporating the patent rights and to develop use, sell, offer to sell and perform processes incorporating the patent rights for all research and therapeutic applications for the term of the MIT License Agreement. Our rights under the license are exclusive in our fields of use, except with respect to (a) MIT and Harvard University (which owns the patent rights jointly with MIT), each of which retain rights for research, teaching and educational purposes on their own behalf and on behalf of all other non-profit research institutions, (b) Howard Hughes Medical Institution, which has an irrevocable, non-exclusive, non-assignable, non-sublicensable, license to use the patent rights for its own research purposes and (c) the federal government, which retains a non-exclusive and non-transferable license to practice any government-funded invention claimed in the patent rights, as provided by law. We also have the right to grant sublicenses to third parties, subject to written agreements containing similar protections of MIT and certain third-party beneficiaries as contained in the agreement.

We are required to use diligent efforts, or cause our affiliates or sublicensees to use diligent efforts, to develop licensed products, to introduce licensed products and processes into the commercial market and, thereafter, to make licensed products and processes reasonably available to the public. In addition, we are obligated to satisfy certain development and commercialization metrics and provide MIT with periodic progress reports. To date, we have met our diligence obligations under the agreement. For example, our collaboration with Roche and the commencement of our SQZ-PBMC-HPV trial meet clinical milestones under the agreement. After the fifth anniversary, and before the sixth anniversary, of the MIT License Agreement, the parties are obligated to discuss additional diligence obligations to continue the development and commercialization of licensed products and processes.

We are obligated to make certain payments to MIT including an up-front license issue fee, annual maintenance fees, clinical milestone payments, running royalties based on net sales (at a rate in the low single digits), reimbursement of patent costs, and sharing of sublicense income. In June of 2019, we agreed with MIT on a payment schedule for the sharing of certain amounts received by us from Roche. MIT prosecutes and maintains the patent rights in close consultation with us and our intellectual property counsel. We also provide certain indemnifications for liabilities arising from claims related to the exercise of our rights under the agreement.

Upon entering into the MIT License Agreement, we paid a nominal license issue fee. We agreed to pay MIT a nominal annual license maintenance fee for each calendar year. Each year's annual license maintenance fee may be credited to running royalties due in the same calendar year. We also agreed to pay MIT milestone payments in an aggregate amount of up to $1.8 million per licensed product or process that achieves certain clinical and regulatory

milestones. Additionally, we agreed to pay royalties based on net sales of the licensed products or processes, at low single-digit rates that vary depending on whether sales are made in the therapeutic or research field. With respect to each sublicensee, we are obligated to pay MIT royalties equal to the lesser of (a) a low single-digit percentage of the sublicensee's net sales and (b) 50% of the running royalties owed to us by the sublicensee. We also agreed to pay MIT a percentage in the mid teens of our annual sublicense income (which does not include income from royalties).

The license will remain in effect until the expiration or abandonment of all issued patents and filed patent applications within the licensed patent rights. The agreement is terminable by us upon six months written notice, provided that we have paid all amounts due to MIT through such termination date, and by MIT for nonpayment of amounts due, our cessation of the business related to the agreement, our uncured material breach of the agreement or a challenge initiated by us of the validity, enforceability or non-infringement of the patents licensed to us under the agreement. In the event of any dispute relating to the agreement, either party may initiate mediation to facilitate a negotiated settlement prior to seeking other legal remedies.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that we believe are commercially important to the development of our business, including by seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in our field.

Our future commercial success depends, in part, on our ability to: (i) obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; (ii) defend and enforce our intellectual property rights, in particular our patents rights; (iii) preserve the confidentiality of our trade secrets; and (iv) 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 product candidates or any future products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

Patents

The patent positions of biotechnology and pharmaceutical 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 will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. We also cannot ensure that patents will issue with respect to any patent applications that we or our licensors may file in the future, nor can we ensure that any of our owned or licensed patents or future patents will be commercially useful in protecting our product candidates. In addition, the coverage claimed in a patent application may be significantly reduced before a patent is issued, 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. See "Risk factors—Risks related to our intellectual property" for a more comprehensive description of risks related to our intellectual property.

In the United States, the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to 5 years but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only 1 patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering the use of products from our intellectual property may be entitled to patent term extensions. If our use of product candidates or the product candidate itself receives FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved use or product candidate. We also intend to seek patent term extensions in any jurisdictions where available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. The duration of patents outside of the United States varies in accordance with provisions of applicable

local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patent portfolio includes more than 40 patent families that we own or have licensed, that have been prosecuted and maintained to potentially secure exclusivity for various SQZ® candidates and platforms through to 2028-2043, without taking into account any patent term adjustments or extensions we may obtain. As of February 27, 2023, our portfolio is comprised of over 147 U.S. and foreign patents (including over 85 patents in various European countries) and over 227 U.S., Patent Cooperation Treaty (international), and foreign patent applications. These applications are designed to provide protection for various SQZ® product candidates and platforms including the Cell Squeeze® technology and current clinical candidates. In addition, these patents and applications contain a suite of claims directed to the SQZ® systems, devices, composition of matter and methods of use, including methods of inducing an immune response, tolerance, treating cancer, treating various autoimmune diseases, and various other diseases.

We diligently evaluate our intellectual property strategy as we develop new platform technologies and product candidates. We are positioned to file additional patent applications based on our patenting strategy, or where we seek to adapt to competition or seize business opportunities. We continue to prosecute our portfolio aggressively.

The Cell Squeeze® Platform

As of February 27, 2023, our Cell Squeeze® platform, which includes the Cell Squeeze® technology, methods and use, apparatus and components, and system, is comprised of 67 U.S. and foreign patents and 49 U.S., Patent Cooperation Treaty (international), and foreign patent applications. The patents and applications in this category are relevant or may be relevant to a variety of SQZ® technologies, platforms, and product candidates.

The Immune Activation Platform

As of February 27, 2023, our immune cell platform, which includes the current SQZ-PBMC-HPV and SQZ-eAPC-HPV clinical candidates as well as confidential candidates and technology, specialized Cell Squeeze® methods and use, as well as clinical formulations and protocols, is comprised of 6 US and foreign patents and 118 U.S., Patent Cooperation Treaty (international), and foreign patent applications.

As of February 27, 2023, our anucleate cell platform, which includes the current SQZ-AAC-HPV clinical candidate as well as confidential candidates and technology, specialized Cell Squeeze® methods and use, as well as clinical formulations and protocols, is comprised of 33 U.S. and foreign patents and 23 U.S., Patent Cooperation Treaty (international), and foreign patent applications.

The Immune Tolerance Platform

As of February 27, 2023, our autoimmune platform, which includes the current TAC technology as well as confidential candidates and technology, specialized Cell Squeeze® methods and use, is comprised of 30 U.S. and foreign patents and 20 U.S., Patent Cooperation Treaty (international), and foreign patent applications.

Exploratory Work

As of February 27, 2023, our earlier research and exploratory work, which includes confidential early-stage project candidates and specialized Cell Squeeze® methods and use, is comprised of 11 U.S. and foreign patents and 21 U.S., Patent Cooperation Treaty (international), and foreign patent applications.

Trademarks

We currently own 35 allowed or registered trademarks in various jurisdictions worldwide, including four registered trademarks in the United States. We have 12 pending trademark applications worldwide, including 10 in the United States. Our trademark portfolio includes the following pending, allowed, or registered marks registered in the United States and certain other countries: Cell Squeeze, SQZ, SQZ Biotech, Empower Cells to Change Lives, SQZ Therapeutics, SQZ Activating Antigen Carriers, SQZ Antigen Carriers, SQZ Tolerizing Antigen Carriers, SQZ TX, SQZ-AC, SQZ-AAC, and SQZ-TAC.

Trade Secrets and Proprietary Information

We rely upon unpatented trade secrets, confidential know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, using confidentiality agreements with applicable collaborators, scientific advisors, employees and consultants. We also have agreements requiring assignment of inventions with our employees and selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Competition

As a clinical-stage biotechnology company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. This competition includes both small companies and large companies with greater financial and technical resources and longer operating histories than our own. We also compete with the intellectual property, technology and product development efforts of academic, governmental and private research institutions.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly if they establish collaborative arrangements with large companies.

The key competitive factors affecting the success of any products that we develop, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may commercialize products more quickly than we do.

We expect to compete with companies using other cell engineering approaches, such as electroporation and viral vectors. Companies that are engineering cells with some of these methods include Fate Therapeutics, which is programming hematopoietic cells and other biotechnology companies working on single cell types.

We expect our SQZ-eAPC-HPV product candidate will compete with other product candidates for the treatment of HPV16+ cancers. While there are currently no FDA-approved therapies that target HPV for HPV+ cancers, there are multiple competing clinical-stage product candidates in development targeting HPV+ cancers. These product candidates include genetically modified T cell therapies in clinical development by Kite, peptide vaccines in clinical development by ISA Pharma, biologics being developed by Cue Biopharma, and nucleic acid vaccines in clinical development by BioNTech and clinical development by Inovio. Therapies that are not specific to HPV are also being explored and applied to HPV+ tumors, including tumor infiltrating lymphocytes developed by Iovance Biotherapeutics and immune checkpoint inhibitors that are approved for treatment in multiple solid tumors.

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 biological product candidates 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. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biologics Regulation

Biological products, including our product candidates, are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act. 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 applicable regulations, including the FDA's good laboratory practice, or GLP, requirements;
- submission to the FDA of an IND which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application, or BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and potential inspection of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. 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 time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the submission of an IND to the FDA, supervision of certain human gene transfer trials may also require evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to the public health or the environment, and such assessment 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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- 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 also 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. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

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 preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to an annual program fee. A waiver of user fees may be obtained under certain limited circumstances, such as for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Once a BLA has been submitted, within 60 days, the FDA first reviews the BLA to determine if it is substantially complete before the FDA 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 filing date. Priority review designation will direct overall attention and resources to the evaluation of applications for products that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious diseases or conditions. In both standard and priority reviews, the review process may be significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions regarding approval.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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 any 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 approval, which with respect to biological products, is referred to as licensure, of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine 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. The FDA may also 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.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several

reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to expedite FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, nw drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, , the FDA may consider sections of the application for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. A fast track-designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would offer a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing.

A product candidate 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 candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate 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.

In addition, under the accelerated approval program, the FDA may approve a BLA for a product candidate intended to treat serious or life-threatening diseases or conditions upon a determination that the product candidate has an effect on either 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 approval, the FDA generally requires that sponsors of a product receiving accelerated approval perform adequate and well-controlled confirmatory trials verify and describe the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the 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. FDA may withdraw approval of a biologic or indication approved under accelerated approval on an expedited basis if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product or if the sponsor fails to conduct such trials in a timely manner.

In 2017, the FDA established the regenerative medicine advanced therapy, or RMAT, which 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 or biologic that meets the following criteria: (i) the biologic 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 biologic is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the biologic 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. Product candidates 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 clinical trial sites, including through expansion of trials to additional sites.

Fast track designation, priority review, accelerated approval, RMAT designation and breakthrough therapy 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.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States 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.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same disease or condition 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 user fee.

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

Post-Approval Requirements

Any products manufactured or distributed 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, annual program fees for any marketed products.

Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon BLA holders and their third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure

to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Exclusivity

The Affordable Care Act, or ACA, signed into law in 2010, includes the Biologics Price Competition and Innovation Act, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed 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, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as

interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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.

FDA Regulation of Companion Diagnostics

Our product candidates may require use of an in vitro diagnostic to identify appropriate patient populations. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. 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, companion diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA.

If use of companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. 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 candidates such as our product candidates, a companion diagnostic device and its corresponding drug or biologic candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. In July 2016, the FDA issued a draft guidance document intended to further assist sponsors of therapeutic products and sponsors of in vitro companion diagnostic devices on issues related to co-development of these products.

The FDA generally requires companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic contemporaneously with approval of the therapeutic. The review of these in vitro companion diagnostics in conjunction with the review of therapeutic candidates such as those we are developing involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The PMA process, including the gathering of clinical and pre-clinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are also subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive pre-clinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. In addition, as part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

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, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will issue an order denying approval of the PMA or issue a not approvable order. 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. PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Other Healthcare Laws

Pharmaceutical manufacturers 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 may include, without limitation, the U.S. federal anti-kickback , fraud and abuse, false claims, consumer fraud, pricing reporting,, and transparency laws and regulations as well as similar state and foreign laws in the jurisdictions outside the U.S. Violation of any such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, reputational harm, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations and exclusion from participation in governmental healthcare programs and imprisonment.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Sales of any pharmaceutical product 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 for such product by third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. The availability of coverage and extent of reimbursement by governmental and private payors are essential for most patients to be able to afford treatments. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. In the U.S., the Medicare program, which is administered by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, is increasingly used as a model for how commercial and other governmental payors develop their own coverage and reimbursement policies for new drugs and biologics. One third-party payor's decision to cover a particular product, however, does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require

manufactures to provide scientific and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. 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, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are more frequently challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products and biologics, in addition to questioning their 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. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented 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; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the United States Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include

work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, absent additional Congressional action.

There has also been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined.

In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. Further regulatory changes include passage of the Right to Try Act on May 30, 2018. The law, among other things, provides a federal framework for certain patients to access certain investigational new medical products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 products and services, which could result in reduced demand for our products once approved or additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital Resources

In connection with the strategic reprioritization and restructuring approved by our Board of Directors on November 30, 2022, we announced a workforce reduction of approximately 60%. We provided affected employees with 60 days' notice that their employment would end on January 30, 2023. Payment of severance and other one-time termination benefits are expected to be substantially completed by the end of the first quarter of 2023. At December

31, 2022, we had 53 full-time and no part-time employees. We have provided both cash and equity-based retention incentives to retain employees following the restructuring. At December 31, 2022, the 53 full-time employees included 10 employees with M.D. or Ph.D. degrees and 37 employees engaged in clinical, research and development, product development and quality assurance activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. We believe our success depends on our ability to attract, retain, develop and motivate highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team, and who provide strategic direction, develop our business, manage our operations and maintain a cohesive and stable work environment. We also rely on highly qualified and skilled employees with technical expertise in operations, scientific knowledge, and quality management experience in order to operate our business successfully. Led by our experienced management team, we believe our strong culture and the disciplined execution of our employees will form the foundation of our success.

Available Information

We were incorporated in March 2013 under the laws of the State of Delaware. We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. We make available on our website at www.sqzbiotech.com, free of charge, copies of these reports and any amendments as soon as reasonably practicable after filing or furnishing them with the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and no history of commercializing cell therapy products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.

We are a clinical-stage biotechnology company. Our operations to date have been limited to financing and staffing our company, developing our technology, and identifying and developing our product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by biotechnology companies in their early stages of operations. We have not yet demonstrated an ability to complete any clinical trials, obtain marketing approval, manufacture a commercial scale product, or conduct sales and marketing activities necessary for successful product commercialization, or arrange for third parties to do these activities on our behalf. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and obtaining marketing approval for and commercializing cell therapies.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will eventually need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in this transition.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

We have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future. We have no products that have generated any commercial revenue and we may never achieve or maintain profitability.

We have incurred significant net losses since our inception, including net losses of $79.5 million and $68.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $275.0 million. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our preclinical development activities and clinical trials of our product candidates.

We expect to continue to incur significant additional operating losses for the foreseeable future as we seek to advance product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete preclinical studies and clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. In order to obtain U.S. Food and Drug Administration, or FDA, approval to market any product candidate in the United States, we must submit to the FDA a biologics license application, or BLA, demonstrating that the product candidate is safe, pure and potent with respect to its intended use. This demonstration requires significant research and animal tests, which are referred to as nonclinical or preclinical studies, as well as human tests, which are referred to as clinical trials. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial and difficult to accurately predict. Because of the numerous risks and uncertainties associated with the development of cell therapies, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- progress our ongoing clinical trials or initiate additional clinical trials of our most advanced product candidates, SQZ-AAC-HPV and SQZ-eAPC-HPV;
- advance the development of or enter into strategic collaborations with respect to other product candidates, including the preclinical development of other product candidates under our Antigen Presenting Cell, or SQZ® APC, platform, our

Activating Antigen Carriers, or SQZ® AAC, platform, our enhanced APCs, or SQZ®eAPC, platform, and our Tolerizing Antigen Carriers, or SQZ® TAC, platform;

- continue to discover and develop additional product candidates using our Cell Squeeze® technology;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain marketing approval;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval, if any, in geographies in which we plan to commercialize our products ourselves;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial and support personnel, to execute our business plan;
- add clinical, scientific operational, financial and management information systems and personnel to support our product development and potential future commercialization efforts;
- utilize external vendors for support with respect to research, development, manufacturing, commercialization, regulatory, pharmacovigilance and other functions;
- acquire or in-license commercial products, additional product candidates and technologies;
- expand internationally;
- make royalty, milestone or other payments under current and any future in-license agreements;
- implement additional internal systems and infrastructure;
- incur additional legal, accounting and other expenses in operating our business; and
- continue to operate as a public company.

Furthermore, our ability to successfully develop, commercialize and license our products and generate product revenue is subject to substantial additional risks and uncertainties. Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to incur operating losses and negative cash flows for the foreseeable future. These operating losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the foreseeable future, and might never generate revenues from the sale of products. Our ability to generate product revenue and achieve profitability will depend on, among other things, successful completion of the clinical development of our product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory authorities; establishing manufacturing, sales, market acceptance of our products, if approved, and marketing infrastructure to commercialize our product candidates for which we obtain approval; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We may not successfully execute or achieve the expected benefits of our strategic realignment plan and other cost saving measures we may take in the future, and our efforts may result in further actions and may adversely affect our business, financial condition and results of operations.

On November 30, 2022, our board of directors approved a strategic realignment plan designed to reduce costs and reallocate resources to concentrate on the development of our eAPC program. The plan includes the release of approximately 60% of our employees. The plan is based on our current estimates, assumptions and forecasts, which are subject to known and unknown risks and uncertainties, including assumptions regarding cost savings and cash burn rate. Accordingly, we may not be able to fully realize the cost savings, enhanced liquidity and other benefits anticipated from the strategic realignment plan. Additionally, implementation of the plan and any other cost-saving initiatives may be costly and disruptive to our business, the expected costs and charges may be greater than we have forecast, and the estimated cost savings may be lower than we have forecast. For example, although we initially paused our AAC program as part of our strategic realignment plan, we subsequently resumed the AAC program in light of the response in the first patient dosed in the SQZ-AAC-HPV clinical trial, which we expect will increase our expenses even though we plan to partially offset

such costs with other cost saving measures. In addition, our initiatives could result in personnel attrition beyond our planned reduction in headcount or reduce employee morale, which could in turn adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods, or our ability to attract highly skilled employees. Unfavorable publicity about us or the strategic realignment plan could result in reputational harm and could diminish confidence in our brand and business. The plan has required, and may continue to require, a significant amount of management's and other employees' time and focus, which may divert attention from effectively operating and growing our business.

We may expend our limited resources on programs that do not yield a successful product candidate or fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our programs and product candidates, we must focus our programs and product candidates on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. For example, in November 2022, we announced that we are undergoing a strategic prioritization of our clinical portfolio designed to reduce costs and reallocate resources to concentrate on the development of our eAPC program. More recently, in light of the response in the first patient dosed, we decided to continue to enroll patients in the SQZ-AAC-HPV clinical trial. Additionally, we may reprioritize product candidate development plans and activities at any time and delay or terminate development of any product candidates we identify. Similarly, our potential decisions to delay, terminate, or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the biotechnology industry, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We will require significant additional funding in order to complete development of and obtain regulatory approval for our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We will require additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Additional sources of financing might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned clinical trials or seek regulatory approvals of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

We will require substantial funds to further develop, seek regulatory approvals for, and if approved, commercialize our product candidates, including SQZ-AAC-HPV, which is currently in Phase 1 clinical development, and SQZ-eAPC-HPV, which is currently in Phase 1/2 clinical development, and all of our future product candidates.

Based on our current operating plan, we believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2024. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of SQZ-AAC-HPV, SQZ-eAPC-HPV and other future product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, approval and any approved marketing and commercialization activities. Our future funding requirements, both near- and long-term, will depend on many factors, including but not limited to:

- the scope, timing and results of our preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for SQZ-AAC-HPV, SQZ-eAPC-HPV and our future product candidates;
- the costs and timing of changes in the regulatory environment and enforcement rules;
- the costs and timing of changes in pharmaceutical pricing and reimbursement infrastructure;

- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including any litigation costs and the results of such litigation;
- the effect of competing technological and market developments;
- the extent to which we enter into additional collaboration arrangements with respect to our product candidates or in-license or acquire other products and technologies;
- the costs related to operating as a public company;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the stability, scale and yield of our future manufacturing process as we scale-up production and formulation of our product candidates for later stages of development and commercialization;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products;
- the initiation, progress, timing and results of our commercialization of SQZ-AAC-HPV, SQZ-eAPC-HPV and our future product candidates, if approved for commercial sale; and
- general economic conditions, such as the recent global economic instability, including as a result of the COVID-19 pandemic, which may adversely impact our business.

Depending on our business performance, the economic climate and market conditions, including market volatility resulting from the COVID-19 pandemic, general economic conditions or other factors, we may be unable to raise additional funds through any sources. If we are unable to obtain adequate funding on a timely basis, we may be required to curtail or discontinue one or more of our development programs for SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates, or to reduce our operations. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience dilution and the terms of any new equity securities may have preference over those of our existing common stock.

We do not currently have sufficient working capital to fund our planned operations for the next twelve months and may not be able to continue as a going concern.

As of March 22, 2023, the issuance date of our consolidated financial statements, included elsewhere in this Annual Report on Form 10-K, our management has concluded that there is substantial doubt about our ability to continue as a going concern, as we currently do not have adequate financial resources to fund our forecasted operating costs for at least twelve months from the filing of this Annual Report on Form 10-K. As of December 31, 2022, we had an accumulated deficit of $275.0 million. During the year ended December 31, 2022, we recorded a net loss of $79.5 million. In addition, during the year ended December 31, 2022 we used $84.0 million in operating and investing activities resulting in a cash and cash equivalents balance of $63.7 million as of December 31, 2022. As a result, absent significant changes to our operating structure, our existing cash resources are not expected to be sufficient to meet our anticipated needs over the next twelve months from the date hereof, and we will need to raise additional capital to continue our operations and to implement our business plan. Although we have been able to raise capital in the past primarily through debt or equity financings and strategic collaborations, there is no assurance that we will be able to obtain additional financing on favorable terms or at all.

If we raise funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. Further, any contracts or license arrangements we enter into to raise funds may require us to relinquish our rights to our products or technology, and we may not be able to enter into any such contracts or license arrangements on favorable terms, or at all. Additionally, our fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates, if approved. Having insufficient funds may require us to delay or scale back our development programs and other activities, revise our business plan and strategy, liquidate certain assets, or cease our operations altogether.
Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our consolidated financial statements included in this

Annual Report on Form 10-K do not include any adjustments to reflect our possible inability to continue as a going concern within one year after the issuance of such financial statements. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. As of March 11, 2023, we had substantially all of our cash and cash equivalents on deposit with SVB or managed by SVB at a separate institution.

Although a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure and we and other depositors with SVB received such access on March 13, 2023, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

Although we have taken steps to mitigate liquidity concerns relating to SVB, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

In addition, if any parties with whom we conduct business are unable to access funds held in uninsured deposit accounts or pursuant to lending arrangements with a financial institution that is placed in receivership by the FDIC, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

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

Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations, our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, redeeming our stock, making certain investments and engaging in certain merger, consolidation or asset sale transactions, among other restrictions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The COVID-19 pandemic has impacted, and will likely continue to impact, our operations and clinical trial execution and may materially and adversely affect our business and financial results in the future.

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce. For example, we have intermittently staggered activity at our principal executive offices and laboratory space located in Watertown, Massachusetts. Although restrictions have eased, we continue to offer flexible schedules and have implemented work-from-home policies.. The effects of these measures may negatively impact productivity, disrupt our business and delay our clinical programs and timelines and future clinical trials. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, results of operations and financial condition, including our ability to obtain financing.

COVID-19 has impacted and may continue to impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. For example, we have experienced delays in receiving supplies of raw materials for our development activities due to the impact of COVID-19 on our suppliers' ability to timely manufacture these materials.

In addition, our clinical trials may be affected by the COVID-19 pandemic and general economic conditions, including:

- delays in receiving authorizations from regulatory authorities to initiate or modify our planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, both in the United States and abroad;
- delays or difficulties in enrolling patients in our clinical trials, including patients who may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruptions in preclinical studies and clinical trial activities due to restricted or limited operations at our or our third-party service providers' laboratory facilities, including the collection and analysis of data, or unavailability of raw materials or parts used in our manufacturing process;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product and biopsy specimens, or make such transport significantly more expensive;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA to accept data from clinical trials in geographies affected by COVID-19.

For example, we have experienced delays in opening clinical trial sites and sites that are open may also have challenges enrolling patients due to the COVID-19 pandemic. The global COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

Risks Related to Discovery, Development, Preclinical and Clinical Testing, Manufacturing and Regulatory Approval

Our business is highly dependent on the success of our product candidates, each of which will require significant additional preclinical and clinical testing before we can seek regulatory approval and potentially launch commercial sales. If our product candidates do not receive regulatory approval or are not successfully commercialized, or are significantly delayed in doing so, our business will be harmed.

A substantial portion of our business and future success depends on our ability to develop, obtain regulatory approval for and successfully commercialize our product candidates, including our most advanced product candidates, SQZ-AAC-HPV, which is currently being evaluated in a Phase 1 clinical trial, and SQZ-eAPC-HPV, which is currently being evaluated in a Phase 1/2 clinical trial. We currently have no products that are approved for commercial sale and have not completed the development of any product candidates, and we may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to SQZ-AAC-HPV, SQZ-eAPC-HPV and other future product candidates which will require additional preclinical and clinical development, management of clinical, medical affairs and manufacturing activities, obtaining regulatory approvals in multiple jurisdictions, securing of manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales from a product candidate, if approved. We cannot be certain that SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates will be successful in ongoing or future clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Even if we receive approval to market SQZ-AAC-HPV, SQZ-eAPC-HPV and/or other future product candidates from the FDA or other regulatory bodies, we cannot be certain that such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Nor can we be certain that, if and when approved, the safety and efficacy profile of SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates will be consistent with the results observed in clinical trials.

If the required regulatory approvals for SQZ-AAC-HPV or SQZ-eAPC-HPV are not obtained or are significantly delayed, or any approved products are not commercially successful, our business, financial condition and results of operations may be materially harmed.

SQZ-AAC-HPV and SQZ-eAPC-HPV are being developed under our SQZ AAC and SQZ eAPC platforms, respectively, and the failure of any of these products to receive regulatory approval could adversely affect other product candidates being developed under those respective technology platforms. Moreover, if we experience similar regulatory or developmental issues with our other pipeline product candidates, our development plans and business could be significantly harmed. Further, our competitors may be developing products with similar mechanisms of action or treating similar indications and may experience problems with their products that could identify problems that would potentially harm our business.

Preclinical and clinical development are lengthy and uncertain, and our preclinical programs or development candidates may be delayed or terminated, or may never advance to the clinic, any of which may affect our ability to obtain funding and may have a material adverse impact on our platforms or our business.

Product candidates in preclinical development or involved in strategic collaborations could be delayed or not advance into the clinic. Before we can initiate clinical trials for a product candidate, we must complete extensive preclinical studies, including in some cases good laboratory practice toxicology testing, that support our planned INDs in the United States, or similar applications in other jurisdictions. We must also complete extensive work on Chemistry, Manufacturing, and Controls, or CMC, activities, including product yield, product purity and product stability data, to be included in the IND submission. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies, and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Further, we may perform preclinical and clinical development activities outside the United States. Conducting preclinical development and clinical trials in foreign countries presents additional risks that may delay development of our product candidates or completion of our clinical trials. These risks include availability of and competition for skilled local personnel, the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to these foreign countries.

We may conduct certain of our clinical trials for our product candidates in sites outside of the United States, including Europe and Asia. However, the FDA and other foreign equivalents may not accept data from foreign trials, in which case our development plans will be delayed, which could materially harm our business.

We may conduct certain of our clinical trials for existing or future product candidates outside the United States, such as in Europe and Asia. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA may not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

For clinical trials that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with the good clinical practice requirements, or GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- additional foreign regulatory requirements;
- variability in expense due to local labor rates, availability of skilled personnel and foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought;
- diminished protection of intellectual property in some countries; and
- international political pressures.

The successful development of cellular therapeutics, such as the product candidates using our Cell Squeeze technology, is highly uncertain.

We have no products approved for commercial sale and have not generated any revenue from product sales. Before we are able to generate any revenue from product sales, our current and future product candidates will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts. The success of our current and future product candidates will depend on several factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- implementing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply and distributor relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- launching and successfully commercializing product candidates for which we obtain marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- obtaining adequate reimbursement from payors for our product candidates or procedures using our product candidates;

- the convenience and durability of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for any of our product candidates that may be approved;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory authorities to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to successfully commercialize a product candidate, we may not become profitable, and we will need to obtain additional funding through one or more equity or debt financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, or the price and available third-party reimbursement are lower than anticipated, we may not generate significant revenue from sales of such products, even if approved.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

Our Cell Squeeze technology is novel. As such, it is difficult to accurately predict the developmental challenges we may incur for our product candidates as they proceed through product discovery or identification, preclinical studies and clinical trials. In addition, because we are currently conducting a Phase 1 clinical trial for SQZ-AAC-HPV and a Phase 1/2 clinical trial for SQZ-eAPC-HPV, , we are continuing to assess the safety of our technology in humans and we have not yet been able to fully assess the efficacy of our technology in humans and there may be short-term or long-term effects from treatment with any product candidates that we develop that we cannot predict at this time. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. Moreover, even if we obtain data from our clinical trials, because the Cell Squeeze technology applied in our programs is novel and has not been externally verified, our data may be difficult to replicate and/or subject to misinterpretation by us or others. As a result of these factors, it is difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our Cell Squeeze technology, or any similar or competitive cellular technologies, will result in the identification, development and regulatory approval of any products. There can be no assurance that any development challenges we experience in the future related to our Cell Squeeze technology or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use as well as market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities and approaches. Further, as we are developing novel treatments, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, few cell therapy products have been approved by the FDA or comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union, or EU, or other jurisdictions. Further, approvals by one regulatory authority may not be indicative of what other regulatory authorities may require for approval.

Regulatory requirements governing cellular therapy products have evolved and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of cellular therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

We are subject to significant regulatory oversight by the FDA and foreign regulatory bodies in jurisdictions where we may seek to develop or commercialize our products. In addition to these government bodies, the applicable Institutional Biosafety Committee, or IBC, Institutional Review Board, or IRB, and similar cell therapy boards of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial.

Changes in applicable regulatory guidelines may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with regulatory authorities and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Cellular therapies are a novel approach and negative perception of any product candidates that we or third parties develop could adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The developmental and commercial success of our current product candidates, or any product candidates that we develop alone or with collaborators in the future, will depend in part on public acceptance of the use of cell therapy technology, including the candidates we are developing using our Cell Squeeze technology, for the prevention or treatment of human diseases. Adverse public perception of cell therapies may negatively impact our ability to raise capital or enter into strategic agreements for the development of product candidates.

Cellular therapy remains a novel technology. The commercial success of our cellular therapy product candidates, if successfully developed and approved, may be adversely affected by claims that cellular therapy is unsafe, unethical or immoral. This may lead to unfavorable public perception and the inability of any of our product candidates to gain the acceptance of the public or the medical community. Unfavorable public perceptions may also adversely impact our or our collaborators' ability to enroll clinical trials for our product candidates.

Our success in commercializing any product candidates that receive regulatory approval will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of cellular therapies, could result in a decrease in demand for any product that we may develop. In addition, responses by the federal, state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, expensive, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be seriously harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other

studies. We have not submitted for or obtained regulatory approval for any product candidate. We must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety, purity and potency (or efficacy) of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or interpretation of results of our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe, pure and potent (or effective), only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use of our products;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the FDA, or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business. In addition, even if we or our collaborators were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS. Regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, regulatory authorities in the EU may not approve the price we or our collaborators intend to charge for products we may develop. Any of the foregoing scenarios could seriously harm our business.

Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects 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 regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval.

If any serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of, or require us to conduct a stock recovery of, cease selling or recall any product candidates or products for any or all targeted indications. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated. Additionally, if one

or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

Clinical development is lengthy and uncertain. We may encounter substantial delays and costs in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time-consuming and subject to uncertainty. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or a clinical trial application, or CTA, will result in the FDA, Health Canada, or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. For example, the FDA initially placed our IND for SQZ-PBMC-APC on clinical hold, pending receipt of additional data related to sterility testing, which was ultimately removed. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments in trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly; or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements, or GCPs, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Any inability to successfully initiate or complete clinical trials, or any delay in an ongoing trial, could result in additional costs to us or impair our ability to generate revenue from product sales. For example, biopsy specimens required as part of our clinical trials may be of insufficient quantity and quality to be properly evaluated due to the impact of COVID-19 on transportation, logistics and staffing at our sites and vendors. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. 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 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 using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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 product revenue. In addition, many 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.

The limited number of patients who have the diseases for which some of our product candidates may be studied, or meet the eligibility criteria of our clinical trials, may make it more difficult for us to enroll or complete such clinical studies, or may result in findings in our clinical studies that do not reach levels of statistical significance sufficient for marketing approval.

There may be limited patient pools from which to draw for clinical studies. In addition to the rarity of these diseases, the eligibility criteria of our clinical studies will further limit some of the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. We may not be able to initiate or continue clinical trials on a timely basis or at all for any of our product candidates if we or our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. Similarly, we plan to design and conduct clinical trials utilizing a limited number of patients in order to evaluate the safety and therapeutic activity of our product candidates. Conducting trials in smaller subject populations increases the risk that any safety or efficacy issues observed in only a few patients could prevent such studies from reaching statistical significance or otherwise meeting their specified endpoints, which could require us to conduct additional clinical studies, or delay or prevent our product candidates from receiving regulatory approval, which would seriously harm our business.

In addition, with respect to clinical trials for certain of our product candidates, such as for SQZ-AAC-HPV or SQZ-eAPC-HPV, there is substantial overlap between the populations of patients who are or would be eligible to be enrolled. If we conduct clinical trials for two or more of our product candidates simultaneously, either by choice or necessity, any patient enrollment in one of the clinical trials may be obtained at the expense of or to the detriment of patient enrollment in the other.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the target disease population;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

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

From time to time, we may publish interim, "topline" or preliminary data from preclinical studies or clinical trials. Such data and related findings and conclusions are subject to change following more comprehensive reviews of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or "topline" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available. As a result, interim, "topline" and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, "topline" or interim data and final data could seriously harm our business.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the

information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the "topline," preliminary or interim data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could seriously harm our business.

We may not be successful in our efforts to identify and successfully develop additional product candidates.

Although we are currently prioritizing our ongoing clinical trials, part of our long-term strategy involves identifying novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third-parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

In addition, we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. There may also be substantial overlap in the addressable market of patients which our product candidates, if approved, would be designed to treat. As a result, in order to reduce an overlap, we may seek to commercialize only certain of our product candidates and may forego commercializing other of our product candidates. If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely 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 products. 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.

We may seek orphan drug designation for certain product candidates, but we may be unable to obtain such designation or to obtain or maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our product revenue, if any, to be reduced.

We may seek orphan product designation for some of our product candidates; however, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product receives the first FDA approval for the disease or condition for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug or biologic for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated disease or condition and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan disease or condition due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same diseases or conditions. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same disease or condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

A fast track Designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

On November 8, 2022, the FDA granted fast track designation for SQZ-eAPC-HPV as a monotherapy and in combination with pembrolizumab for the treatment of HPV16+ recurrent, locally advanced, or metastatic solid tumors with disease progression following prior lines of systemic therapy to improve overall survival. We intend to seek such designation for some or all of our other product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, biologic product candidates are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a fast track product candidate 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 application.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation for any of our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that SQZ-eAPC-HPV or any other product candidate that may be granted fast track designation will receive regulatory approval in the U.S. Many product candidates that have received fast track designation have ultimately failed to obtain approval.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable

authorities in other countries. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. Our development programs are early-stage and we have not received approval to market any product candidates from regulatory authorities in any jurisdiction. It is possible that none of the product candidates we are developing or that we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs, suppliers, vendors or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

Both in the United States and abroad, the process of obtaining marketing approvals, if approval is obtained at all, is expensive, may take many years, especially if additional clinical trials are required and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate product revenue will be materially impaired.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

We are developing a product candidate, and in the future may develop other product candidates, in combination with other therapies, which exposes us to additional risks.

SQZ-AAC-HPV is being evaluated in a Phase 1 clinical trial and SQZ-eAPC-HPV is being evaluated in Phase 1/2 clinical trial, , and each of these candidates is designed to treat HPV16+ tumors as a monotherapy and in combination with other immune-oncology agents. In the future, we may develop product candidates to be used with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval or subsequent commercial success.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of our oncology product candidates as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

Our product candidates, if approved, may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product.

We believe that any of our investigational products approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, funding of other government agencies that finance research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved or licensed biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays Regulatory authorities outside the United States may adopt similar restrictions or other policy measures or reallocate resources in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it 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 insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, umbrella, clinical trial, cyber and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval SQZ-AAC-HPV, SQZ-eAPC-HPV and/or other future product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operating as a public company has and will continue to make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our business and operations may suffer in the event of information technology system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we directly or indirectly collect and store sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information and personal information, including health-related information, of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance and transmission of this information is critical to our operations. However, our information technology systems, as well as those of our CROs and other contractors and consultants, are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic and the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. Although, to our knowledge, we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, our networks and the information stored there could be accessed, publicly disclosed, lost or stolen and it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical studies or clinical trial data from completed, ongoing or planned studies or trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidate could be delayed. Any such access, disclosure or other loss of information could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties. Any such event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our business, financial condition, results of operations. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective equivalents outside of the United States. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling our products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct preclinical studies and clinical trials. We or our collaborators must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy, potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any

approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, consultants, CMOs, CROs or other vendors, fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

Enacted and future healthcare legislation and policies may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and could adversely affect our business.

In the United States, the EU, Asia and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could prevent or delay marketing approval of our products in development, restrict or regulate post-approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement and impact our ability to sell any such products profitably. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

In March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the United States Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as outcomes-based reimbursement. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. In March 2021, Congress enacted the American Rescue Plan Act of 2021, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In Asia, comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs, could also affect our ability to receive marketing approval or commercialize our product candidates. For example, in order to conduct a clinical trial in China, sponsors must not only obtain the approval of the National Medical Product Administration of China, but also a separate approval from or filing with the Ministry of Science and Technology under the HGR Regulation for clinical trials involving HGR Materials or Information. Any failure to comply with these requirements could cause a clinical trial to be suspended by governing authorities and may result in fines. In recent years, the regulatory framework in Asia regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes, which may prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States, the EU, and Asia, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In addition, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU, Asia or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny and post-marketing requirements.

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practice, or cGMP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products "off-label" for indications or uses for which they do not have approval, though we may share truthful and not misleading information that is otherwise consistent with our product's FDA approved labeling. The holder of an approved application, such as a BLA, must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval or label restrictions.

If the FDA or another regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States

or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are and will be subject to applicable healthcare regulatory 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. Such laws include:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit, offer, receive, pay or provide any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false, fictitious or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; the Federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in Asia, the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above 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, 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to applicable data privacy, protection and security laws, regulations, standards and other requirements, and our actual or perceived failure to comply with such obligations could harm our business, results of operations and financial condition.

We are subject to diverse laws and regulations relating to data privacy and security, including in the United States, in the EU and the European Economic Area, or EEA, and in Asia. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. In the United States, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe we are currently classified as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Moreover, patients about whom we or our collaborators obtain health-related information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, or CCPA, took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain

personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our clinical trial programs outside the United States may implicate international data protection laws, including the General Data Protection Regulation, or GDPR, and legislation of the EU member states implementing it. The GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20 million or up to 4% of our total global annual revenue in the event of a significant breach or non-compliance. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, we have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Furthermore, in Asia, some countries are implementing or considering GDPR-like data protection laws. For example, in China, on June 10, 2021, the Standing Committee of the PRC National People's Congress published the Data Security Law of the People's Republic of China, or the Data Security Law, which took effect on September 1, 2021. The Data Security Law requires data processing (which includes the collection, storage, use, processing, transmission, provision and publication of data), to be conducted in a legitimate and proper manner. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities and also introduces a data classification and hierarchical protection system based on the importance of data in economic and social development and the degree of harm it may cause to national security, public interests, or legitimate rights and interests of individuals or organizations if such data are tampered with, destroyed, leaked, illegally acquired or illegally used. The appropriate level of protection measures is required to be taken for each respective category of data.

Also in China, on August 20, 2021, the Standing Committee of the National People's Congress of the PRC promulgated the Personal Information Protection Law, which took effect on November 1, 2021. The Personal Information Protection Law raises the protection requirements for processing personal information, and many specific requirements of the Personal Information Protection Law remain to be clarified. We may be required to make further significant adjustments to our business practices to comply with the personal information protection laws and regulations in China, including the Personal Information Protection Law, or in other jurisdictions in Asia.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Further, if we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase

the costs and expenses of developing, commercializing and marketing our products. Any failure or perceived failure by us or our employees, representatives, CMOs, CROs, contractors, consultants, collaborators, or other third parties to comply with data privacy and security requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Changes in tax laws may impact our future financial position and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. For example, the Tax Cuts and Jobs Act of 2017, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act of 2022 enacted many significant changes to the U.S. tax laws. In particular, for tax years beginning after December 31, 2021, the Tax Cuts and Jobs Act of 2017 eliminates the once available option to deduct research and development expenditures currently and requires taxpayers to amortize them generally over five years. We are unable to predict whether any further changes will occur and, if so, the ultimate impact on us or our business. To the extent that such changes have a negative impact on us or our business, these changes may materially and adversely impact our financial condition, results of operations and cash flows.

Risks Related to Commercialization

Developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets.

Our industry has been characterized by extensive research and development efforts, rapid developments in technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical, biotechnology and specialty pharmaceutical companies either marketing or developing cell therapies or biologic or small molecule modalities for patients with cancer and other serious diseases. Academic research institutions, governmental agencies and public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Many of these competitors may also have compounds already approved or in development in the therapeutic categories that we are targeting with our current and future product candidates. In addition, many of these competitors, either alone or together with their collaborative partners, may operate larger research and development programs or have substantially greater financial resources than we do, as well as greater experience in:

- developing product candidates;

- undertaking preclinical testing and clinical trials;
- obtaining BLA approval by the FDA;
- comparable foreign regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing and selling products.

If these competitors access the marketplace before we do with safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products.

Our product candidates are intended to compete directly or indirectly with existing products and products currently in development. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians or patients. Hospitals, physicians or patients may conclude that our potential products are less safe or effective or otherwise less attractive than these existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Significant competition additionally exists in the treatment of cancer and other serious diseases for which we are developing our cell therapies. We will need to compete with all currently available or future therapies within the indications where our development is focused. SQZ-AAC-HPV and SQZ-eAPC-HPV, if approved and commercialized, will face significant competition with other product candidates for the treatment of HPV+ cancers. While there are currently no FDA-approved therapies that target HPV for HPV+ cancers, there are multiple competing clinical-stage product candidates in development targeting HPV+ cancers. These product candidates include genetically modified T cell therapies in clinical development, peptide vaccines in clinical development, and nucleic acid vaccines in clinical development. Therapies that are not specific to HPV are also being explored and applied to HPV+ tumors, including tumor infiltrating lymphocytes and immune checkpoint inhibitors that are approved for treatment in multiple solid tumors.

In addition, we generally expect to compete with companies using other cell engineering approaches, such as electroporation and viral vectors, including a biotechnology company that is genetically engineering red blood cells, a biotechnology company that is programming hematopoietic cells and other biotechnology companies working on single cell types. In addition, we also expect to compete more generally with companies developing biologic or small molecule modalities.

Many of our competitors have substantially greater capital resources, robust product candidate pipelines, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. As a result, our competitors may achieve product commercialization or patent protection earlier than we can. 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 clinical, regulatory, scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or noncompetitive.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by

governmental and private payors is essential for most patients to be able to afford treatments. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive 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. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program is increasingly used as a model for how private and other governmental payors develop their coverage and reimbursement policies for new drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the EU and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, if approved, and we may not be able to generate any product revenue.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so.

We may build our own focused sales, distribution and marketing infrastructure to market SQZ-AAC-HPV, SQZ-eAPC-HPV and future product candidates, if approved, in the United States and other markets around the world. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates, if approved. Additionally, if the

commercial launch of SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our future products;
- our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to develop or obtain sufficient operational functions to support our commercial activities; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may not have the resources in the foreseeable future to allocate to the sales and marketing of SQZ-AAC-HPV, SQZ-eAPC-HPV or any future product candidates in the United States or in markets outside of the United States. Therefore, our future sales in these markets may largely depend on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. For example, in October 2018, we entered into the Roche License and Collaboration Agreement, or the Roche Agreement, under which we are collaborating with Roche in the development and commercialization of certain antigen products.

If we are unable to build our own sales force or access a collaborative relationship for the commercialization of SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates, we may be forced to delay the potential commercialization of SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates or reduce the scope of our sales or marketing activities for such product candidates. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to any of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, even if we do establish adequate sales, marketing and distribution capabilities, the progress of general industry trends with respect to pricing models, supply chains and delivery mechanisms, among other things, could deviate from our expectations. If these or other industry trends change in a manner which we do not anticipate or for which we are not prepared, we may not be successful in commercializing our product candidates or become profitable.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries, we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;

- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- our ability to supply our product candidates on a timely and large-scale basis in local markets;
- longer lead times for shipping which may necessitate local manufacture of our product candidates;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

If SQZ-AAC-HPV, SQZ-eAPC-HPV or any future product candidates is approved for commercialization, we intend to selectively partner with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries, including requirements specific to biologics or cell therapy products;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- political unrest and wars, such as the current situation with Ukraine and Russia, which could delay or disrupt business activity, and if such political unrest escalates or spills over to or otherwise impacts additional regions, it could heighten many of the other risk factors included in this Item 1A; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by the EU and many of the individual countries in Europe, as well as countries in Asia such as China and Taiwan, with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products internationally to be very challenging.

Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations.

In some countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the

cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

The use of our product candidates, including SQZ-AAC-HPV and SQZ-eAPC-HPV, in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize SQZ-AAC-HPV, SQZ-eAPC-HPV or any future product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for SQZ-AAC-HPV, SQZ-eAPC-HPV or any future product candidate, if approved for commercial sale; and
- loss of revenue.

Risks Related to Our Dependence on Third Parties

The Roche Agreement is important to our business. If we or Roche fail to adequately perform under the Roche Agreement, or if we or Roche terminate the Roche Agreement, the development and commercialization of certain of our product candidates could be materially delayed and our business would be adversely affected.

Under the Roche Agreement, Roche is jointly responsible for the clinical development, with Roche being primarily responsible for the late-stage clinical development of certain potential product candidates. We and Roche may be jointly responsible for conducting global clinical studies and coordinating commercial launch activities.

Termination of the Roche Agreement, in whole or in part, could cause significant delays in any development and commercialization efforts we undertake for our SQZ APC platform in oncology. If the Roche Agreement is terminated, we would need to expand our internal capabilities or enter into another agreement to compensate for the loss in funding and clinical development support from Roche. Any suitable alternative agreement would take considerable time to negotiate and could also be on less favorable terms to us. Whether or not we identify another suitable collaborator, we would need to seek additional financing to continue the development of our SQZ APC platform in oncology, or we may be forced to discontinue development of our SQZ APC platform in oncology either of which could have a material adverse effect on our business. Presently, we have discontinued the SQZ APC platform in favor of the second generation eAPC platform.

In addition, under the Roche Agreement, we also agreed to use commercially reasonable efforts to mutually select and generate additional preclinical data on additional antigens other than the HPV targeted SQZ-PBMC-HPV to develop collaboratively. With respect to each mutually selected antigen, we granted Roche an option, exercisable after we supply Roche with a clinical proof of concept for a product containing the antigen, to obtain an exclusive license of our intellectual property to exploit the product worldwide for the treatment of oncologic indications using our SQZ APC platform and a microfluidic chip. Roche granted us an option, exercisable with respect to every alternating mutually selected antigen product for which Roche exercises its own option, beginning with the second, to obtain an exclusive license of Roche's intellectual property to exploit the antigen product in the United States. If we exercise our option to obtain, or if this alternating option structure otherwise results in our obtaining, exclusive licenses with respect to antigen products that we are subsequently unable to exploit or otherwise unsuccessful in developing and commercializing, our business could be materially harmed.

Even if the Roche Agreement is adequately performed by us and Roche, any success of our product candidates subject to the agreement may be obtained at the expense of or to the detriment of our other wholly owned product candidates, which could limit our profitability.

There may be substantial overlap in the addressable market of patients which our product candidates, if approved, would be designed to treat. As a result, in order to reduce an overlap, we may seek to commercialize only certain of our product candidates and may forego commercializing other of our product candidates. Furthermore, such an overlap may exist between certain of our potential product candidates, such as SQZ-PBMC-HPV, that are subject to the Roche Agreement, and other of our product candidates, such as SQZ-AAC-HPV, which are wholly owned. Therefore, even if the Roche Agreement is adequately performed by us and Roche and we are able to successfully commercialize a product candidate, such success may be obtained at the expense of or to the detriment of our other wholly owned product candidates, which could limit our profitability.

We rely on third parties for the manufacture of raw materials and product candidates for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

Although we currently conduct certain manufacturing operations internally for preclinical studies, we rely on third parties for the manufacture of raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We do not have a long-term agreement with many of the third-party manufacturers we currently use to provide preclinical and clinical raw materials, and we purchase any required materials on a purchase order basis. Certain of these manufacturers are critical to our production and the loss of these manufacturers to one of our competitors or otherwise, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent or impair our ability to timely conduct preclinical studies or clinical trials, and would materially and adversely affect our development and commercialization efforts.

The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities and may limit or restrict our clinical supply of product candidates and ability to supply any approved products to the market. Some of our contract manufacturers may not have produced a commercially approved product and therefore may not have previously obtained the requisite FDA approvals to do so. As such, regulatory authorities may identify compliance gaps or violations in the future, including if and when these contract manufacturers seek approval to manufacture and supply commercial product. In addition, we have limited control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our desired schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers may be affected, which could disrupt their activities and as a result we could face difficulty timely sourcing key components necessary for the manufacture of our product candidates and other materials, which may negatively affect our preclinical studies and clinical trials as well as other relationships and business plans. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We do not have multiple sources of supply for some of the components used in our product candidates, nor long-term supply contracts, and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates. If we obtain regulatory approval for our product candidates, we would need to expand the supply of components in order to commercialize them.

We do not have multiple sources of supply for each of the components used in the manufacturing of our product candidates, including SQZ-AAC-HPV and SQZ-eAPC-HPV. We also do not have long-term supply agreements with all of our component suppliers. We may not be able to establish additional sources of supply for our product candidates or may be unable to do so on acceptable terms. Manufacturing suppliers are subject to cGMP quality and regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates and subject to ongoing inspections by applicable regulatory authorities. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions in supply. Manufacturing suppliers are also subject to local, state and federal regulations and licensing requirements. Failure by any of our suppliers to comply with all applicable regulations and requirements may result in long delays and interruptions in supply.

The number of suppliers of the raw material components of our product candidates is limited. In the event it is necessary or desirable to acquire supplies from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company and redesign of processes can trigger the need for conducting additional studies such as comparability or bridging studies. Additionally, certain of our suppliers are critical to our production, and the loss of these suppliers to one of our competitors or otherwise would materially and adversely affect our development and commercialization efforts. Furthermore, suppliers have been experiencing and may continue to experience shortages, delayed shipments, surcharges and other supply chain issues caused by or related to the COVID-19 pandemic. COVID-19 restrictions have also led to a shortage of personnel to manufacture, package and ship supplies and consumables, further limiting the available supply. If our suppliers are not able to obtain materials needed for our product candidates in preclinical studies and clinical trials, there may be a material adverse impact on our business and financial condition.

As part of any marketing approval, regulatory authorities conduct inspections that must be successful prior to the approval of the product. Failure of manufacturing suppliers to successfully complete these regulatory inspections will result in delays. If supply from the approved supplier is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through a BLA amendment or supplement, which could result in further delay. The FDA or other regulatory authorities outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of , SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates or, if we obtain regulatory approval for SQZ-AAC-HPV, SQZ-eAPC-HPV or other future product candidates, to commercialize them.

We rely on third parties to conduct our preclinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to GCPs and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We are dependent on third parties to conduct critical aspects of our preclinical studies and clinical trials, including in our clinical trials for SQZ-AAC-HPV and SQZ-eAPC-HPV, and we expect to rely on third parties to conduct future clinical trials and preclinical studies for our other pipeline product candidates. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of

our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Any third parties conducting our clinical trials or preclinical studies are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any BLA we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We have collaborated and, in the future, may collaborate with third parties for the development and commercialization of our candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

We have collaborated and, in the future, may seek collaborative relationships for the development and commercialization of our product candidates. For example, we have entered into a collaborative relationship with Roche. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate product revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into. Collaborations involving our product candidates pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information inappropriately or in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may 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;
- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices, materials, know-how or intellectual property of the collaborator relating to our product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We

may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

If we seek, but are not able to establish, collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future product revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant product revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any current or future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration, which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights

licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce such licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

Data provided by collaborators and others upon which we rely that have not been independently verified could turn out to be false, misleading or incomplete.

We rely on third-party vendors, such as CROs, scientists and collaborators to provide us with significant data and other information related to our projects, preclinical studies or clinical trials and our business. For example, in connection with the clinical development of our product candidates, we may rely on data provided by third parties with respect to combination therapies. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of preclinical studies or clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 such laws or regulations. For example, we are currently evaluating certain exploratory preclinical experiments conducted by a former employee based on employee allegations of potential data integrity concerns. While these preclinical experiments do not relate to our product candidates in clinical trials or those for which we have submitted, or plan to submit, INDs, limited data from these experiments have been published or were incorporated in applications and interim reports for government grants that we have been awarded. We are following the review process required by the administrators of the grants and our internal policies to evaluate these data. While the amount we have received from these grants has not been significant, we are unable to predict the impact this evaluation may have on these grants, including the possibility that we may need to repay the funds we have received. We also have informed the journal in which a portion of the data was published about our investigation and the journal has issued an editorial expression of concern. We are unable to predict what further action, if any, the journal may take or the timing of such action, and we may decide or be asked to update, correct or retract the article in which the data appeared. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, including in connection with the ongoing evaluation described above, and we are not successful in defending ourselves or asserting our rights, those actions could potentially have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, restitution, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Generally, we do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from duplicating SQZ-AAC-HPV, SQZ-eAPC-HPV, and any future product candidates.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal, factual and scientific questions and can be uncertain. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge the inventorship, ownership, validity, enforceability or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create new products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold with respect to our programs or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize future products. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate.

Furthermore, if third parties have filed such patent applications before enactment of the Leahy-Smith Act on March 16, 2013, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for the patent covering a product, we may be open to competition from generic competing products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our product

candidate, if approved, or practicing our own patented technology. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is either not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. If any of our trade secrets are disclosed to a competitor or other third party, we are likely to lose trade secret protection.

Although we require all of our employees and consultants to assign their inventions to us, to the extent that employees or consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Further, although we require that all of our employees, consultants, collaborators, advisors and any third parties who have access to our proprietary know-how, information or technology enter into confidentiality agreements, we cannot provide any assurances that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently discover our trade secrets or develop substantially equivalent information and techniques. Any of these parties may breach these agreements and we may not have adequate remedies for any specific breach. Misappropriation or unauthorized disclosure of our trade secrets or other confidential proprietary information could impair our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets or other confidential proprietary information are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret or other confidential proprietary information.

If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement, or allegations of infringement, of the patents and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination, and *inter partes* review proceedings before the United States Patent and Trademark Office, or USPTO, and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to composition of matter, drug delivery, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We cannot guarantee that our technologies, products, compositions and their uses do not or will not infringe third-party patent or other intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. If any third-party patents were held by a court of competent jurisdiction to cover the composition of matter of any of our product candidates, the manufacturing process of any of our product candidates, the method of use for any of our product

candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, which may not be available or may not be available on commercially reasonable terms, or until such patents expire.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of the merit of such claims. We may not be aware of all intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates and/or harm our reputation and financial results. Defense of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of management and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, in the case of claims concerning registered trademarks, rename our product candidates, or obtain one or more licenses from third parties, which may require substantial time and monetary expenditure, and which might be impossible or technically infeasible. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. 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 obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements or seek damages from us, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

Although we or our licensors are not currently involved in any relevant litigation, we may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensors' patents, trademarks, copyrights or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims against third parties. It may be difficult to detect infringers who do not advertise the components

that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. To counter infringement or unauthorized use, we may be required to file infringement claims on a country-by-country basis, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded.

Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

In any such proceeding, a court may decide that a patent of ours, or a patent that we in-license, is not valid, is unenforceable and/or is not infringed, or may construe such patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or held unenforceable, could put our patent applications at risk of not issuing, and could limit our ability to assert those patents against those parties or other competitors and curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs, and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Recent patent reform legislation has increased the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, and may diminish the value of patents in general.

As is the case with other biopharmaceutical companies, our commercial success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Recent wide-ranging patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase those uncertainties and costs.

The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. Under The Leahy-Smith Act, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. The Leahy-Smith Act also enlarged the scope of disclosures that qualify as prior

art, and it expanded the scope of procedures that a third party may use to challenge a U.S. patent, including post-grant review and inter partes review procedures. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, recent court rulings in cases such as *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, and *Promega Corp. v. Life Technologies Corp.* have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or our ability to hire personnel, which, in any case of the foregoing, could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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 non-compliance with these requirements.

The USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market, which could have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation.

Such mechanisms include re-examination, post-grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business. A defendant could also challenge our ownership of patents assigned to us. We cannot be certain that a third party would not challenge our rights to these patents and patent applications. Any legal proceeding or enforcement action can also be expensive and time-consuming.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. 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. For patents that are eligible for extension of patent term, we expect to seek extensions of patent terms in the United States and, if available, in other countries. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate product revenue.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuit that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements) or 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 the patent.

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

While we seek to protect the trademarks we use in the United States and in other countries, we may be unsuccessful in obtaining registrations and/or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands

and trademarks unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we fail to comply with our obligations in our intellectual property licenses with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to license agreements that impose, and we may enter into additional licensing arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing arrangements, we are obligated to pay royalties based on net sales of product candidates or related technologies to the extent they are covered by the agreements. We are also obligated to make certain milestone and license maintenance fee payments to licensors. If we fail to comply with such obligations under current or future licensing agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate that is being developed under such agreement, or for which research, development or commercialization depends on rights licensed to us under such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Disputes which may arise regarding intellectual property subject to a licensing agreement include, but are not limited to:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of patented inventions.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-license. If other third parties have ownership rights to patents and/or patent applications we in-license, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our proprietary rights may not adequately protect our technologies and product candidates, and 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. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own;
- others, including inventors or developers of our patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications;
- we might not have been the first to file patent applications covering certain of our patents or patent applications;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;
- our issued patents may not provide us with any commercially viable products or competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our collaboration partners' patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory and clinical affairs and sales, marketing, manufacturing and distribution. To manage our growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage

the expansion of our operations or recruit and train additional qualified personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow product revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer.

We are highly dependent on our management and directors, including our Interim Chief Executive Officer, Howard Bernstein, among others. Due to the specialized knowledge each of our officers and key employees possesses with respect to our product candidates and our operations, the loss of service of key officers or directors could delay or prevent the successful enrollment and completion of our clinical trials. We do not carry key person life insurance on our officers or directors. In general, the employment arrangements that we have with our executive officers do not prevent them from terminating their employment with us at any time.

In addition, our future success and growth will depend in part on the continued service of our directors, employees and management personnel and our ability to identify, hire and retain additional personnel. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees, including the roles of Chief Executive Officer and Chief Financial Officer, may be difficult or costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or effectively incentivize these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Additionally, competition for talent in the pharmaceutical and biotechnology industry has become increasingly intense. There was, and continues to be, a dramatic increase in workers leaving their positions throughout our industry and the U.S. economy that is being referred to as the "great resignation," and the market to build, retain and replace talent has become even more highly competitive. Furthermore, common stock and common stock option awards to employees may not serve as a valuable retention tool as a result of the volatility in the price of our common stock and in the stock market generally and in the market for smaller biotechnology companies in particular. Our future success depends on our ability to continue to attract and retain talented executive officers and other key employees.

Furthermore, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Risks Related to Our Common Stock

An active, liquid trading market for our common stock may not be sustained.

There can be no assurance that we will be able to maintain an active trading market for our common stock on the New York Stock Exchange, or the NYSE, or any other exchange. On January 18, 2023, we were notified by the NYSE that we are not in compliance with Rule 802.01C of the NYSE Listed Company Manual because the average closing price of our common stock was less than $1.00 over a consecutive 30-trading-day period.

Under NYSE rules, we have a period of six months from receipt of the NYSE Notification to cure the stock price deficiency and regain compliance with the NYSE's continued listing standards. The notice has no immediate impact on the listing of our common stock, which will continue to be listed and traded on the NYSE during the period allowed to regain compliance, subject to our compliance with other listing standards. We informed the NYSE that we intend to cure the deficiency and to return to compliance with

the NYSE continued listing requirements. If an active market for our common stock is not maintained, or if we fail to satisfy the continued listing standards of the NYSE for any reason and our common stock is delisted, it may be difficult for our stockholders to sell their common stock without depressing the market price for our common stock, or at all. For example, the NYSE continued listing standards require that our average market capitalization be not less than $15 million over a 30 day trading period, which is a minimum threshold for continued listing with no cure period. Further, an inactive trading market may also impair our ability to raise capital by selling our securities, to attract and motivate employees through equity incentive awards, or to acquire other companies, products, or technologies by using our securities as consideration.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Based on the number of shares of common stock outstanding as of March 11, 2023, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 52% of our outstanding voting stock. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, 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. As of March 11, 2023, we have 29,491,125 outstanding shares of common stock. Of these shares, holders of an aggregate of 2,869,294 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the stockholders' agreement between us and such holders. We have also registered shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements referred to above.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of our initial public offering, or IPO, in 2020. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in the previous three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. In particular, in this Annual Report on Form 10-K, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and certain executive compensation information and the option to present only two years of audited financial statements in our Annual Report on Form 10-K. In addition, for as long as we are a smaller reporting company with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

Provisions in our restated certificate of incorporation and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- the required approval of the holders of at least two-thirds of the shares entitled to vote thereon to (i) effect a reorganization, recapitalization, share exchange, share classification, consolidation, conversion or merger, (ii) sell, lease, exchange, transfer or otherwise dispose of all or substantially all of our assets, or (iii) dissolve our company or revoke a dissolution of our company;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Our ability to use our net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had gross U.S. federal net operating loss carryforwards, or NOLs, of $185.2 million, which may be available to offset future taxable income, if any, of which $11.3 million begin to expire in 2035 and of which $173.9 million do not expire but are generally limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2022, we had gross state NOLs of $174.1 million, which may be available to offset future taxable income, if any, of which $171.8 million begin to expire in 2035 and $0.7 million may be carried forward indefinitely. As of December 31, 2022, we also had federal and state research and development credit carryforwards of $10.4 million and $6.2 million, respectively, which will begin to expire in 2034 and 2030, respectively. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership by certain shareholders or groups of shareholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 and limitations on our ability to utilize NOLs and research and development credit carryforwards following any such ownership change. For these reasons, we may not be able to utilize a material portion of the NOLs or research and development credit carryforwards even if we attain profitability.

General Risk Factors

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biotechnology and pharmaceutical companies in particular have experienced extreme volatility in recent months that has often been unrelated to the operating performance of particular companies. This volatility is likely to continue. As a result of this volatility, our stockholders may not be

able to sell their common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;
- developments related to our existing or any future collaborations;
- developments concerning our contract manufacturers and third-party suppliers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of third-party product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- significant lawsuits, including patent or stockholder litigation;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, CMOs, or other third-party providers may not survive an economic downturn or recession. As a result, our business, results of operations and price of our common stock may be adversely affected.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

We are a public company required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. As an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To achieve compliance with Section 404 within the prescribed period, we have been engaged in a process to document and evaluate our internal control over financial reporting, which has been, and will continue to be, both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We may discover significant deficiencies or material weaknesses in our internal control over financial reporting, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 refined our disclosure controls and procedures to provide reasonable assurance 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, 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. 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.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be the sole source of gain for our stockholders.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common shares would be the sole source of gain on an investment in our common shares for the foreseeable future.

We could be subject to securities class action litigation.

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

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses will increase after we are no longer an emerging growth company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and

financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. For example, operating as a public company has made and will continue to make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If securities or industry analysts do not continue to publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts continue coverage of us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation may suffer. In addition, we may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients or vendors of our customers, or stockholders.

Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may seriously harm our business, overall financial condition and results of operations. Insurance may not cover existing or future claims, be sufficient to fully compensate us for one or more of such claims or continue to be available on terms

acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby adversely impacting our results of operations and resulting in a reduction in the trading price of our stock.

We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause or to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties.

Our principal office is located at 200 Arsenal Yards Blvd, Suite 210, Watertown, MA 02472, where we lease approximately 63,477 square feet of office and laboratory space. We lease this space under a lease agreement, as amended, that terminates on November 30, 2029. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information for Common Stock

Our common stock has been publicly traded on The New York Stock Exchange under the symbol "SQZ" since the initial public offering, or IPO, of our common stock on October 30, 2020. Prior to that time, there was no public market for our common stock. As of March 11, 2023, there were 54 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended December 31, 2022.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company focused on unlocking the full potential of cell therapies to benefit patients with cancer, and other serious medical conditions. The company was founded on the therapeutic potential of Cell Squeeze®, our proprietary technology which allows for rapid delivery of a variety of cargo into different cell types. We aim to create multiple cell therapies that drive the immune system to combat diseases.

On November 30, 2022, our Board of Directors approved a restructuring plan and strategic prioritization of our clinical portfolio (the Restructuring Plan) to concentrate on the development of our second-generation enhanced Antigen Presenting Cells (eAPC) cell therapy program, focused on HPV16 positive recurrent, locally advanced, or metastatic solid tumors and reduce our workforce by approximately 60%. In connection with the prioritization decision, we announced that Armon Sharei, PhD, stepped down from his role as Chief Executive Officer and as a member of the Board of Directors, as of November 30, 2022. The Board appointed Howard Bernstein, MD, PhD, our former Chief Scientific Officer and current director, as Interim Chief Executive Officer.

Additionally, on November 30, 2022, we announced a pause of our Antigen Presenting Cells (APC), Activating Antigen Carrier (AAC) and Tolerizing Antigen Carrier (TAC) programs. This portfolio prioritization allows us to deliver initial data readouts for the SQZ® eAPC program's highest-dose monotherapy cohort, which we anticipate in mid-2023. We will continue to explore partnerships and collaborations for our earlier stage assets and programs, including TAC, as well as our point-of-care manufacturing capabilities.

In oncology, we are developing cell therapy platforms that are based on directing tumor antigen-specific immune activation via engineered antigen presentation. We believe that by engineering physiological antigen presentation signals in subsets of peripheral blood cells that act on immune priming pathways, we have the potential to develop cell therapies that are designed to be potent drivers of tumor-specific immunity, well-tolerated, administered without lymphodepleting preconditioning or hospitalization, and produced in under 24 hours.

We have continued to build upon the progress of our SQZ® APC platform through the development of the novel SQZ® eAPC platform. Our lead eAPC product candidate leverages the added capabilities and functionality of multiple antigen presentation and immunological signals achieved through multiplexed mRNA delivery to diverse immune cell types. In January 2022, we received allowance to proceed with clinical trials from the U.S. Food and Drug Administration, or FDA, under our Investigational New Drug, or IND, application for SQZ-eAPC-HPV, our lead eAPC candidate engineered with HPV16 antigens and costimulatory signals. We initiated the SQZ-eAPC-HPV trial, the COMMANDER-001 Phase 1/2 study, in patients with HPV16+ advanced solid tumors in the first half of 2022. We expect to announce initial data from highest-dose monotherapy cohort in this trial in mid-2023.

Recent Developments

At the time of the November 2022 strategic realignment announcement, the SQZ-AAC-HPV trial had one patient in the lowest- dose cohort on study. On December 21, 2022, after two treatment cycles, the patient's CT scan showed reduction of the target lesion—a right hilar lymph node—from 16 millimeters (mm) at baseline to 10mm, or approximately 38% from baseline, which was consistent with a partial response by RECIST 1.1 criteria. A subsequent scan on February 2, 2023, after four treatment cycles, showed further reduction of the target lesion to 8mm, or 50% from baseline, which was consistent with a confirmed partial response / unconfirmed complete response by RECIST 1.1 criteria, as well as an unconfirmed complete response. In March 2023, after seven cycles of SQZ-AAC-HPV, a CT scan confirmed the complete response by RECIST 1.1 criteria. Biomarker analysis on this patient identified an inflamed tumor microenvironment that highly expressed MHC1 cells and an increase in CD8+ cell density was observed. In light of this response in the first patient dosed, we decided to continue to enroll patients in the SQZ-AAC-HPV clinical trial. The company has completed the dose-limiting toxicity period for the lowest-dose cohort. Following review and recommendation by the Study Safety Committee, the Company is advancing SQZ-AAC-HPV-101 trial to the highest-dose cohort. The company anticipates initial clinical data from the highest-dose cohort in the fourth quarter of 2023.

The ENVOY-001 trial is a Phase 1 open-label trial of our AAC HPV therapy candidate, or SQZ-AAC-HPV, as a monotherapy and in combination with immune checkpoint inhibitors in HLA-A*02+ patients with HPV16+ recurrent, locally advanced or metastatic solid

tumors.

NYSE Notification

On January 18, 2023, we received notice (the "NYSE Notification") from the New York Stock Exchange ("NYSE") indicating that we are not in compliance with Section 802.01C of the NYSE Listed Company Manual ("Section 802.01C") because the average closing price of our common stock was less than $1.00 over a consecutive 30 trading-day period. The NYSE Notification does not result in the immediate delisting of our common stock from the NYSE.

We have notified the NYSE of our intent to cure the stock price deficiency and return to compliance with the NYSE continued listing standards. Under NYSE rules, we have a period of six months from receipt of the NYSE Notification to cure the stock price deficiency and regain compliance with the NYSE's continued listing standards. Our common stock will continue to be listed and trade on the NYSE during this cure period, subject to our compliance with other NYSE continued listing standards. If our common stock is delisted, it may be difficult for our stockholders to sell their common stock without depressing the market price for our common stock, or at all. See Part I, Item 1A. "Risk Factors—An active, liquid trading market for our common stock may not be sustained" in this Annual Report on Form 10-K.

Financial Overview

Since our inception, we have focused substantially all of our resources on building our Cell Squeeze technology, establishing and protecting our intellectual property portfolio, conducting research and development activities, developing our manufacturing process and manufacturing product candidate materials, preparing for and initiating clinical trials of our product candidates, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from sales of common and preferred stock, payments received under our collaboration agreements with Hoffman-La Roche Inc. and F. Hoffman La Roche Ltd., or together, Roche, and with proceeds from our initial public offering, or IPO, and follow-on offering of common stock, or the Follow-On Offering. In November 2020, we completed our IPO pursuant to which we issued and sold 5,073,529 shares of common stock, inclusive of 661,764 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds of approximately $75.5 million from the IPO, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which were $2.6 million. In February 2021, we completed a public offering, or the Follow-On Offering, pursuant to which we issued and sold 3,000,000 shares of common stock. We received aggregate net proceeds of approximately $56.4 million, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which were $0.8 million. On November 10, 2021,we entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") to issue and sell up to $75,000,000 in shares of our common stock from time to time during the term of the Sales Agreement through an "at-the-market" equity offering program under which Jefferies acts as our sales agent (the "ATM Facility"). During the year ended December 31, 2022, we sold 1,261,226 shares of common stock under the ATM Facility for net proceeds of approximately $4.1 million.

Since our inception, we have incurred significant operating losses. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. We reported a net loss of $79.5 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of $275.0 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct clinical trials for our product candidates, including our ongoing clinical trials of SQZ-AAC-HPV and SQZ-eAPC-HPV, predominantly in the United States;
- further develop our Cell Squeeze technology;
- continue to develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific, manufacturing and commercial personnel;
- expand external and/or establish internal commercial manufacturing sources and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- acquire or in-license other product candidates and technologies;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel to support our product development, clinical execution and planned future commercialization efforts, as well as to support our operation as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Currently, market conditions in the biotechnology sector are challenging due to ongoing global and economic uncertainties. Accordingly, we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we would have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 22, 2023, the issuance date of the consolidated financial statements for the year ended December 31, 2022, included elsewhere in this Annual Report on Form 10-K, based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future and the need to raise additional capital to finance future operations, our management has concluded that there is substantial doubt about our ability to continue as a going concern for a period of one year from the date that the condensed consolidated financial statements are issued. See "—Liquidity and Capital Resources."

Impact of the COVID-19 Pandemic

The COVID-19 pandemic has impacted and may continue to impact personnel at third-party manufacturing facilities or the availability or cost of materials, which would disrupt our supply chain. It also has affected and may continue to affect our ability to enroll patients in and timely complete our ongoing clinical trial of SQZ-eAPC-HPV and SQZ-AAC-HPV and delay the initiation of future clinical trials, disrupt regulatory activities or have other adverse effects on our business and operations. For example, we have experienced delays in receiving supplies of raw materials for our preclinical and clinical activities due to the impact of COVID-19 on our suppliers' ability to timely manufacture these materials, and we have experienced an increase in the transportation cost of our product candidates. In addition, we have experienced delays in opening clinical trial sites and sites that are open may also have challenges enrolling patients. Further, staff shortages, including staff that are required to conduct certain testing, such as biopsies, at our clinical sites or at third-party vendors have resulted in delays in site initiations and in some tests not being properly or timely performed or being delayed.

The pandemic, general economic conditions and related uncertainties have caused significant disruptions in the financial markets, and may continue to cause disruptions, which could impact our ability to raise additional funds to support our operations. Moreover, the pandemic has significantly impacted inflation and economies worldwide and could result in adverse effects on our business and operations. We continue to monitor the potential impact of the COVID-19 pandemic on our business and financial statements. To date, we have not incurred impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our consolidated financial statements. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and people. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, financial condition, and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain.

Other developments

We are monitoring ongoing events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally. This includes Silicon Valley Bank, or SVB, which was closed by the California Department of Financial Protection and Innovation, which then appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver on March 10, 2023. As of March 10, 2023, we had substantially all of our cash and cash equivalents on deposit with SVB or managed by SVB at a separate institution. Based upon the announcement on March 12, 2023, from the U.S. Department of the Treasury, the U.S. Federal Reserve and the FDIC, we expect to have access to all of our deposits at SVB and the separate institution. We are also monitoring the impacts that these events may have on our vendors. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Inflation, together with increased interest rates, may cause our customers to reduce or delay orders for our goods and services thereby causing a decrease in or change in timing of sales of our products and services. The impact of future inflation and interest rate fluctuations on the results of our operations cannot be accurately predicted.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to do so for the next several years. All of our revenue to date has been derived from three collaboration agreements with Roche, which we entered into in 2015, 2017 and 2018, and, to a lesser extent, from government grants.

If our development efforts for our product candidates are successful and result in regulatory approval or license or additional collaboration agreements with third parties, we may generate revenue in the future from product sales, payments from additional collaboration or license agreements that we may enter into with third parties, or any combination thereof. We expect that our revenue for the next several years will be derived primarily from our collaboration agreements with Roche as well as any additional collaborations that we may enter into in the future. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all.

Collaboration Revenue

2017 License and Collaboration Agreement with Roche

In April 2017, we entered into a second license and collaboration agreement with Roche, or the 2017 Roche Agreement, to allow Roche to use our Cell Squeeze technology to enable gene editing of immune cells to discover new targets in cancer immunotherapy. The 2017 Roche Agreement includes several licenses granted by Roche to us and by us to Roche in order to conduct a specified research program in accordance with a specified research plan.

Under the agreement, we received an upfront payment of $5.0 million as a technology access fee and are entitled to (i) payments of up to $1.0 million as reimbursement for our research costs; (ii) milestone payments of up to $7.0 million upon the achievement of specified development milestones; and (iii) annual maintenance fees ranging from $0.5 million to $0.9 million for each year following the fifth anniversary of the effective date, subject to specified prepayment discounts.

In early 2022, all active work streams under the 2017 Roche Agreement were concluded and the agreement was terminated. As of December 31, 2021, we determined that we expected to incur no additional costs to satisfy the remaining performance obligations under the 2017 Roche Agreement and we recognized revenue of $1.2 million under the 2017 Roche Agreement. There was no remaining deferred revenue under the 2017 Roche Agreement as of December 31, 2021.

2018 License and Collaboration Agreement with Roche

In October 2018, we entered into a third license and collaboration agreement with Roche, or the 2018 Roche Agreement, to jointly develop certain products based on mononuclear antigen presenting cells, or APCs, including human papilloma virus, or HPV, using our SQZ APC platform for the treatment of oncology indications. We granted Roche a non-exclusive license to our intellectual property, and Roche granted us a non-exclusive license to its and its affiliates' intellectual property for the purpose of performing research activities. In connection with this agreement, the parties terminated the original Roche Agreement entered into in 2015.

Under the 2018 Roche Agreement, Roche was granted option rights to obtain an exclusive license to develop APC products or products derived from the collaboration programs on a product-by-product basis in oncology and to develop a Tumor Cell Lysate, or TCL, product. For each of the APC products and TCL product, once Roche exercises its option and pays a specified incremental amount, Roche will receive worldwide, exclusive commercialization rights for the licensed products, subject to our alternating option to retain U.S. APC commercialization rights. Through December 31, 2022, Roche had not exercised any of its options under the 2018 Roche Agreement.

Under the 2018 Roche Agreement, we received an upfront payment of $45.0 million and are eligible to receive (i) reimbursement of a mid double-digit percentage of our development costs; (ii) aggregate milestone payments on a product-by-product basis of up to $1.6 billion upon the achievement of specified milestones, consisting of up to $217.0 million of development milestone payments, up to $240.0 million of regulatory milestone payments and up to $1.2 billion of sales milestone payments; and (iii) tiered royalties on annual net sales of APC and TCL products licensed under the agreement at specified rates ranging from a mid single-digit percentage to a percentage in the mid twenties. We received the upfront payment of $45.0 million in October 2018 upon execution of the agreement. In addition, during the second quarter of 2019, we received a payment of $10.0 million following the achievement of the first development milestone under the 2018 Roche Agreement related to submission by us of preclinical data to the FDA and during the first quarter of 2020, we received a payment of $20.0 million following the achievement of the second development milestone under the 2018 Roche Agreement related to first-patient dosing in a Phase 1 clinical trial. In the fourth quarter of 2021, we became entitled to receive a milestone payment of $3.0 million upon (i) the recommendation by an independent panel that we could advance our SQZ-PBMC-HPV clinical trial to combination therapy with checkpoint initiators and (ii) the initiation of that therapy. For additional information on the 2018 Roche Agreement, see "Business—Collaboration, Research and License Agreements—Roche Collaboration."

We assessed our accounting for the 2018 Roche Agreement in accordance with ASC 606 and identified the following promises under the agreement: (i) a non-exclusive license granted to Roche to use our intellectual property and collaboration compounds to conduct research activities related to the research plans under the 2018 Roche Agreement; (ii) specified research and development services related to HPV through Phase 1 clinical trials under a specified research plan; (iii) manufacturing of our SQZ APC platform and equipment in order to support the HPV research plan; (iv) specified research and development services on next-generation APCs under a research plan; (v) specified research and development services on TCL under a research plan; and (vi) participation on a joint steering committee, or JSC. We concluded at the outset of the 2018 Roche Agreement that there were three performance obligations under the agreement: (1) the license to our intellectual property, the research and development activities related to HPV through Phase 1 clinical trials under a specified research plan, and the manufacturing of our SQZ APC platform and equipment in order to support the HPV research plan, or the first performance obligation; (2) the license to our intellectual property and the research and development activities on next-generation APCs, or the second performance obligation; and (3) the license to our intellectual property and the research and development activities on TCL, or the third performance obligation. We also concluded that the JSC participation had an immaterial impact on the accounting model.

In addition, we determined that the upfront payment of $45.0 million as well as the reimbursable costs of $10.8 million estimated by us constituted the entirety of the consideration to be included in the transaction price. This transaction price of $55.8 million was initially allocated to the three performance obligations based on the relative standalone selling price of each obligation. The potential milestone payments that we may be eligible to receive were excluded from the transaction price at the outset of the arrangement. We reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, we will adjust our estimate of the transaction price.

We separately recognize revenue associated with each of the three performance obligations as the research, development and manufacturing services are provided using an input method, based on the cumulative costs incurred compared to the total estimated costs expected to be incurred to satisfy each performance obligation. The amounts received from Roche that have not yet been recognized as revenue are deferred as a contract liability in our consolidated balance sheet and will be recognized over the remaining research and development period until each performance obligation is satisfied.

In 2019, we evaluated our overall program priorities and determined that in 2020 we would continue to focus our resources on progressing the specified APC programs related to the 2018 Roche Agreement as well as our AAC and TAC platforms. As a result of our continuing focus on these specific programs, we reduced the level of priority of the TCL research activities under the 2018 Roche Agreement and expect to perform such TCL research activities over a longer time period than as originally expected under the research plan of the agreement. In the fourth quarter of 2022, we determined that based on our internal plans which have not included work on TCL since 2019, and which do not anticipate performing additional work on TCL prior to the expiration of the option right, as well as Roche's concurrence that no work was performed or expected to be performed in 2023, that we could recognize the deferred revenue of $9.2 million. Accordingly, as of December 31, 2022, there was no deferred revenue associated with the TCL performance obligation.

During the year ended December 31, 2022, there were no significant changes in the total estimated costs expected to be incurred to satisfy the performance obligations under the 2018 Roche Agreement. During the year ended December 31, 2021, the total estimated costs expected to be incurred to satisfy the performance obligations decreased by $7.3 million. We recognized revenue of $21.0 million and $25.8 million during the years ended December 31, 2022 and 2021, respectively, under the 2018 Roche Agreement. As of December 31, 2022 and 2021, we recorded as a contract liability deferred revenue related to the 2018 Roche Agreement of $0.2 million and $21.2 million, respectively, of which $0.2 million and $12.0 million, respectively, were current liabilities. As of December 31, 2022, the research and development services related to the remaining performance obligation was expected to be performed over a remaining period of three to six months.

For additional information regarding our accounting for the three collaboration agreements with Roche, see "—Critical Accounting Policies and Significant Judgments and Estimates—Revenue Recognition for License and Collaboration Arrangements" and "Business—Collaboration, Research and License Agreements—Roche Collaboration."

Grant Revenue

We generate revenue from a government contract with the National Institutes of Health (NIH), which reimburses us for certain allowable costs for funded projects, plus an agreed upon fee. Revenue from government grants is recognized as the qualifying expenses related to the contracts are incurred, provided that there is reasonable assurance of recoverability. Revenue recognized upon incurring qualifying expenses in advance of receipt of funding is recorded as unbilled receivables, a component of prepaid expenses and other current assets, in our consolidated balance sheet

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including development of our product candidates and costs incurred under our collaboration arrangements with Roche, which include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates and research programs, including under agreements with third parties, such as consultants, contractors and contract research organizations, or CROs;
- the costs of developing and scaling our manufacturing process and of manufacturing our product candidates for use in our preclinical studies and clinical trials, including the costs under agreements with third parties, such as consultants, contractors and contract manufacturing organizations, or CMOs as well as developing our point-of-care manufacturing system;
- laboratory and consumable materials and research materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and utilities; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered. Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Our direct research and development expenses are tracked on a program-by-program basis and consist of external costs and fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development and manufacturing activities. Such program costs also include the external costs of laboratory and consumable materials and costs of raw materials that are directly attributable to and incurred for any single program. We do not allocate employee costs, costs associated with our platform development and discovery efforts, payments made under third-party licensing agreements, costs of laboratory supplies and consumable materials that are not directly attributable to any single program, and facilities expenses, including rent, depreciation and other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future, particularly should Roche determine not to exercise its options and we decide to continue clinical development of a product candidate. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to raise the additional funds necessary to complete preclinical and clinical development of our product candidates;
- the progress of the development efforts of parties with whom we have entered, or may enter, into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of specialty raw materials for use in production of our product candidates;
- our ability to consistently manufacture our product candidates for use in clinical trials;
- our ability to establish and operate a manufacturing facility, or secure manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally; and

- our ability to protect our rights in our intellectual property portfolio.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. In addition, we may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Restructuring Charges

Restructuring charges consist primarily of salary continuance, severance, continued medical benefits, stock-based compensation expense, depreciation expense and other costs, as a result of the Restructuring Plan approved by our Board of Directors on November 30, 2022. The Restructuring Plan included a strategic prioritization of our clinical portfolio to concentrate on the development of our second-generation enhanced Antigen Presenting Cells (eAPC) cell therapy program and included a workforce reduction of approximately 60%. The workforce reduction affected both research and development and general and administrative functions. We may incur additional costs not currently contemplated due to events that may occur because of, or that are associated with, the Restructuring Plan.

Other Income (Expense)

Interest Income

Interest income consists of interest earned on our cash equivalents balances.

Other Income (Expense), Net

Other income (expense), net consists of miscellaneous income and expense unrelated to our core operations.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each year or for our earned 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 net operating loss, or NOL, carryforwards and tax credit carryforwards will not be realized. As of December 31, 2022, we had U.S. federal NOL carryforwards of $185.2 million, which may be available to offset future taxable income, of which $11.3 million begin to expire in 2034 and of which $173.9 million do not expire but are generally limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2022, we had state NOL carryforwards of $174.1 million, which may be available to offset future taxable income, of which $171.8 million begin to expire in 2035 and $0.7 million may be carried forward indefinitely. As of December 31, 2022, we also had U.S. federal and state research and development tax credit carryforwards of $10.4 million and $6.2 million which will begin to expire in 2034 and 2030, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	YEAR ENDED DECEMBER 31,		
	2022	2021	CHANGE
	(in thousands)		
Collaboration revenue	$ 21,029	$ 27,098	$ (6,069)
Grant revenue	449	—	449
Total revenue	21,478	27,098	(5,620)
Operating expenses:			
Research and development	70,984	70,148	836
General and administrative	26,319	25,719	600
Restructuring charges	4,859	—	4,859
Total operating expenses	102,162	95,867	6,295
Loss from operations	(80,684)	(68,769)	(11,915)
Other income (expense):			
Interest income	1,223	36	1,187
Other expense, net	(3)	(8)	5
Total other income, net	1,220	28	1,192
Net loss	$ (79,464)	$ (68,741)	$ (10,723)

Revenue

Collaboration revenue was $21.0 million for the year ended December 31, 2022, compared to $27.1 million for the year ended December 31, 2021. We recognize revenue under our collaboration arrangements using an input measure, comparing our cumulative costs incurred to our total estimated costs of the research, development and manufacturing activities, as applicable, on each program. The net decrease in collaboration revenue of $6.1 million was due to the following:

- An increase in the expected remaining performance period of the 2018 Roche Agreement at the end of 2021, resulting in a longer period over which revenue was recognized in 2022 compared to 2021.
- In the fourth quarter of 2021, we became entitled to receive a milestone payment of $3.0 million upon (i) the recommendation by an independent panel that we could advance our SQZ-PBMC-HPV clinical trial to combination therapy with checkpoint initiators and (ii) the initiation of that therapy. We achieved both requirements in the fourth quarter of 2021 and we therefore included the $3.0 million milestone payment in our estimate of the transaction price for the 2018 Roche Agreement. As a result, we recorded a cumulative catch-up adjustment to collaboration revenue of $2.5 million during the three months and year ended December 31, 2021.
- A decrease in revenue recognized under the 2017 Roche Agreement. During the year ended December 31, 2022, we recognized no revenue compared to $1.2 million during the year ended December 31, 2021, respectively, under the 2017 Roche Agreement.

Offsetting the above decreases:

- In the fourth quarter of 2022, we determined we could recognize the remaining deferred revenue of $9.2 million related to the TCL performance obligation. This determination was based on our internal plans which have not included work on TCL since 2019, and which do not anticipate performing work on TCL prior to the expiration of the option right, as well as Roche's concurrence that no work was performed or expected to be performed in 2023.

During the years ended December 31, 2022 and 2021, we recognized total revenue of $21.0 million and $25.8 million, respectively, under the 2018 Roche Agreement.

The decrease in collaboration revenue for the year ended December 31, 2022 was partially offset by a $0.4 million increase in grant revenue. We were awarded a government grant by the NIH at the end of the first quarter of 2022 and began performing services under this grant during the second quarter of 2022.

Research and Development Expenses

	YEAR ENDED DECEMBER 31,		
	2022	2021	CHANGE
	(in thousands)		
Direct research and development expenses by program:			
SQZ-PBMC-HPV	$ 8,711	$ 15,751	$ (7,040)
SQZ-AAC-HPV	6,760	3,873	2,887
SQZ-eAPC-HPV	13,546	15,071	(1,525)
Other programs	10,229	7,372	2,857
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	22,064	18,408	3,656
Facility related	5,281	5,173	108
Laboratory and consumable materials	1,178	1,430	(252)
Platform-related external services and other	3,215	3,070	145
Total research and development expenses	$ 70,984	$ 70,148	$ 836

Research and development expenses were $71.0 million for the year ended December 31, 2022, compared to $70.1 million for the year ended December 31, 2021. The net increase was primarily due to the following:

- Direct costs incurred for our SQZ-AAC-HPV program increased by $2.9 million primarily as a result of an increase in allocated manufacturing costs and clinical trial-related costs partially offset by reduced technology transfer costs.
- Other program costs increased by $2.9 million primarily due to expenses incurred on developing a point-of-care system to manufacture our product candidates, as well as development of other platform related programs.
- The increase in personnel-related costs of $3.7 million was primarily due to increased headcount and salary costs in our research and development function prior to the November 2022 Restructuring Plan. Personnel-related costs for the year ended December 31, 2022 and 2021 included stock-based compensation expense of $3.3 million and $3.2 million, respectively.
- Facility-related costs increased by $0.1 million primarily due to an increase in operational costs.

Partially offsetting the above increases were:

- The direct costs related to our SQZ-PBMC-HPV program decreased by $7.0 million primarily due to lower manufacturing costs as we increased our clinical trial activity on other product candidates.
- SQZ-eAPC-HPV costs decreased by $1.5 million primarily due to a decrease in allocated and direct manufacturing costs, partially offset by an increase in clinical trial-related costs.
- Laboratory and consumable materials expenses for general usage fluctuate from period to period based on the timing of our purchases made. We expense the costs of materials when purchased because they have no alternative future use. The laboratory and consumables materials expenses decreased by $0.3 million during the year ended December 31, 2022 compared to the year ended December 31, 2021.

General and Administrative Expenses

	YEAR ENDED DECEMBER 31,		
	2022	2021	CHANGE
	(in thousands)		
Personnel related (including stock-based compensation)	$ 12,885	$ 12,685	$ 200
Professional and consultant fees	5,795	6,054	(259)
Facility related and other	7,639	6,980	659
Total general and administrative expenses	$ 26,319	$ 25,719	$ 600

General and administrative expenses for the year ended December 31, 2022 were $26.3 million, compared to $25.7 million for the year ended December 31, 2021. The increase in general and administrative expenses was primarily due to the following:

- Personnel-related costs increased by $0.2 million primarily due to an increase in salary costs due to an increase in headcount as well as an increase in stock-based compensation expense. Personnel-related costs for the years ended December 31, 2022 and 2021 included stock-based compensation expense of $4.7 million and $5.3 million, respectively.
- Facility related and other costs increased by $0.7 million primarily due to an increase in operational costs.

Partially offsetting the increase was a decrease in professional and consultant fees of $0.3 million due to lower legal related costs incurred during 2022 in comparison to 2021.

Restructuring Charges

	YEAR ENDED DECEMBER 31,		
	2022	2021	CHANGE
	(in thousands)		
Personnel related (including salaries, severance and other benefits)	$ 3,983	$ —	$ 3,983
Stock-based compensation	381	—	381
Depreciation expense	422	—	422
Facility related and other	73	—	73
Total restructuring charges	$ 4,859	$ —	$ 4,859

Restructuring charges for the year ended December 31, 2022 were $4.9 million, compared to $0 for the year ended December 31, 2021. The increase in restructuring charges was primarily due to the following:

- Personnel-related costs increased by $4.0 million primarily due to salary continuation, one-time severance payments, and other employee-related separation costs including stock-based compensation expense.
- Stock-based compensation expense increased by $0.4 million due to modifications of stock options to extend the period for exercising vested options post-separation.
- Depreciation expense increased by $0.4 million due to accelerated depreciation expense as a result of reducing the estimated useful lives and accelerating the depreciation expense for certain laboratory equipment that will no longer be required and will be disposed of.

Interest Income

Interest income for the years ended December 31, 2022 and 2021 was $1.2 million and less than $0.1 million, respectively. The increase in interest income was due to an increase in interest rates despite lower average cash balances during 2022 as compared to 2021.

Other Income (Expense), Net

Other income (expense) was not significant for both the years ended December 31, 2022 and 2021.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for the next several years, if at all. Through December 31, 2022, we have funded our operations from the sales of our common and preferred stock, upfront and milestone payments under our collaboration agreements with Roche, and with proceeds from our IPO, Follow-On Offering and our ATM Facility. In November 2020, we completed our IPO pursuant to which we issued and sold 5,073,529 shares of common stock, inclusive of 661,764 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds of approximately $75.5 million, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which were $2.6 million. In February 2021, we completed the Follow-On Offering pursuant to which we issued and sold 3,000,000 shares of common stock. We received aggregate net proceeds of approximately $56.4 million, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which were approximately $0.8 million. As of December 31, 2022, we had cash and cash equivalents of $63.7 million. During the year ended December 31, 2022, we raised approximately $4.1 million in net proceeds, under the ATM Facility, pursuant to which we sold 1,261,226 shares of our common stock. See Note 1 to our consolidated financial statements.

Going Concern

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any products and we do not expect to generate revenue from sales of any products for several years, if at all. As of December 31, 2022, our cash and cash equivalents were $63.7 million and our restricted cash balance was $2.3 million. We expect

that our research and development and general and administrative expenses will continue to be significant as we focus on completing the necessary development, obtaining regulatory approval and preparing for potential commercialization of our product candidates. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2024.

These conditions and events raise substantial doubt about our ability to continue as a going concern for the one-year period following the issuance of our consolidated financial statements for the year ended December 31, 2022. To finance our operations, we will need to raise additional capital, which cannot be assured. Unless and until we reach profitability in the future, we will require additional capital to fund our operations, which could be raised through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations and strategic alliances. If we are unable to obtain funding, we could be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which would adversely affect our business prospects, or we may be unable to continue operations.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	YEAR ENDED DECEMBER 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (83,549)	$ (82,137)
Net cash used in investing activities	(488)	(613)
Net cash provided by financing activities	4,233	55,906
Net decrease in cash, cash equivalents and restricted cash	$ (79,804)	$ (26,844)

Operating Activities

During the year ended December 31, 2022, operating activities used $83.5 million of cash, primarily resulting from our net loss of $79.5 million and changes in our operating assets and liabilities of $24.2 million partially offset by net non-cash charges of $20.1 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2022 consisted of increases resulting from: a $3.0 million decrease in accounts receivable due to a milestone payment from Roche, a $2.1 million increase in accrued expenses, and a $3.2 million increase in accrued restructuring expenses offset by: a $0.4 million increase in prepaid expenses and other current assets, a $1.4 million decrease in accounts payable, a $20.9 million decrease in deferred revenue and a $9.9 million decrease in operating lease liabilities.

During the year ended December 31, 2021, operating activities used $82.1 million of cash, primarily resulting from our net loss of $68.7 million and changes in our operating assets and liabilities of $32.9 million partially offset by net non-cash charges of $19.5 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted of a $1.1 million increase in accounts receivable, a $0.5 million decrease in prepaid expenses and other current assets, a $1.0 million increase in accounts payable, a $23.8 million decrease in deferred revenue and a $8.7 million decrease in operating lease liabilities.

In all periods presented, other changes in prepaid expenses and other current assets, accounts receivable, accounts payable, accrued expenses and other liabilities not described above were generally due to growth in our business, the advancement of our research programs and the timing of vendor invoicing and payments. In all periods presented, decreases in operating lease liabilities were primarily due to our recurring payments made under recorded operating lease liabilities, including those arising from embedded leases.

Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was $0.5 million, consisting of purchases of property and equipment.

During the year ended December 31, 2021, net cash used in investing activities was $0.6 million, consisting of purchases of property and equipment.

The purchases of property and equipment in each period were primarily for equipment purchases related to the expansion of our research and development activities and the growth of our business.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $4.2 million, consisting primarily of net proceeds from the ATM Facility, employee stock purchase plan issuances, and stock option exercises during the year.

During the year ended December 31, 2021, net cash provided by financing activities was $55.9 million, consisting primarily of net proceeds from our Follow-On Offering of $55.6 million and stock option exercises of $1.3 million, offset by the payment of issuance costs for prior period IPO common stock issuances of $1.1 million.

Funding Requirements

Even with the expected reduction in research and development and general and administrative expenses as a result of the Restructuring Plan announced on November 30, 2022, we expect that substantial expenses will be incurred in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. In addition, we expect to continue to incur additional costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend largely on:

- our ability to successfully execute upon and achieve the expected benefits of our Restructuring Plan
- the timing and progress of preclinical and clinical development activities;
- the commencement, enrollment or results of the current clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- the timing and outcome of regulatory review of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial as well as Roche's decision whether to exercise its options;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers and other third-party providers;
- our ability to obtain materials to produce adequate product supply for any approved product or inability to do so at acceptable prices;
- the identification of additional restructuring charges not currently contemplated due to events that may occur because of, or that are associated with the Restructuring Plan.
- our ability to establish collaborations if needed;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval;
- the legal patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; and
- the severity, duration and impact of the COVID-19 pandemic and general economic conditions, which may adversely impact our business.

As of December 31, 2022, we had cash, cash equivalents and marketable securities of $63.7 million. In accordance with Accounting Standards Update ("ASU, 2014-15"), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), we are required to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern from the issuance date of our financial statements. Based on our current plans, which reflect the anticipated effect of the Restructuring Plan approved by our Board of Directors on November 30, 2022, including the 60% workforce reduction, certain cost reducing activities including pausing certain clinical trial activity and exploratory research programs, we believe that our existing cash, and cash equivalents will enable us to fund our operating expenses into the first quarter of 2024.

This timeline is subject to uncertainty as to the timing of future expenditures. We have developed plans to mitigate this risk, which primarily consist of raising additional capital through some combination of equity or debt financings, potential new collaborations, and/or reducing cash expenditures. If we are not able to secure adequate additional funding, we plan to make additional reductions in spending. In that event, we may have to delay, scale back, or eliminate some or all of our planned clinical trials. The actions necessary to reduce spending under this plan at a level that mitigates the factors described above are not considered probable, as defined in the accounting standards and therefore, the full extent to which management may extend our funds through these actions may not be considered in management's assessment of our ability to continue as a going concern. As a result, management has concluded that substantial doubt exists about our ability to continue as a going concern.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' interests will be

diluted, and the terms of these securities may include liquidation or other preferences that adversely affect an investor's rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, including due to adverse macroeconomic conditions such as rising interest rates, we would be required to delay, scale back or discontinue our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Under license agreements with MIT, we are obligated to pay annual license fees and to make contingent milestone and royalty payments. Under our license agreement with MIT, we are obligated to make aggregate milestone payments of up to $1.8 million upon the achievement of specified milestones, consisting of up to $0.8 million of development milestone payments and up to $1.0 million of regulatory milestone payments, as well as to pay royalties of low single-digit percentages of (i) our, and any of our affiliates' and sublicensees', net sales of licensed products in the research field and (ii) our, and any of our affiliates', net sales of licensed products in the therapeutic field. In addition, we are obligated to pay annual license maintenance fees of less than $0.1 million per year. For additional information on our license with MIT, see "Business—Collaboration, Research and License Agreements—MIT License Agreement."

Under our license agreement with Erytech, we are obligated to make aggregate milestone payments of up to $6.0 million upon the achievement of specified milestones, consisting of up to $1.0 million of development milestone payments and up to $5.0 million of regulatory milestone payments, for the first licensed product to achieve the specified milestones and payments of up to $50.0 million upon the achievement of specified sales milestones for all licensed products successfully developed under the agreement for each indication. In addition, we are obligated to pay tiered royalties ranging in the low single-digit percentages of annual net sales for each licensed product or licensed indication sold by us or our affiliates.

Under the 2018 Roche Agreement, if Roche exercises one of its options, then for each antigen product candidate for which Roche commercializes outside of the United States and we commercialize in the United States, we are obligated to pay Roche tiered royalties on net sales of such product candidate in the United States. The amount, timing and likelihood of such payments are not known. See "Business—Collaboration, Research and License Agreements—Roche Collaboration."

We enter into contracts in the normal course of business with CMOs, CROs and other third parties for preclinical research studies, manufacturing, clinical trials, services and testing. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

For additional information regarding our contractual commitments, see Notes 9 and 10 of our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition for License and Collaboration Arrangements

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, 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 in the contract; and (v) recognize revenue when, or as, we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine which goods or services are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, that performance obligation is satisfied.

We enter into licensing arrangements that are within the scope of ASC 606, under which we may exclusively license to third parties rights to research, develop, manufacture and commercialize our product candidates. The terms of these arrangements typically include payment to us of one or more of the following: nonrefundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and sales milestone payments; and royalties on net sales of licensed products. The payment terms under our existing licensing arrangements are 60 days.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our arrangements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the assessment of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, we satisfy each performance obligation. As part of the accounting for these arrangements, we must use significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. We also use judgment to determine whether milestone payments or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price, as described below. The transaction price is allocated to each performance obligation based on the relative standalone selling prices of each performance obligation in the contract, and we recognize revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. We estimate the standalone selling price of each of the identified performance obligations in our customer contracts, maximizing the use of observable inputs. Because we have not sold the same goods or services in our contracts separately to any customers on a standalone basis and there are no similar observable transactions in the marketplace, we estimate the standalone selling price of each performance obligation in our customer arrangements based on our estimate of costs to be incurred to fulfill our obligations associated with the performance, plus a reasonable margin.

We have determined that our only contract liability under ASC 606 is deferred revenue. Amounts received prior to revenue recognition are recorded as deferred revenue in the consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion, in the consolidated balance sheets.

Exclusive Licenses

If the license to our intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, we recognize revenue from nonrefundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, we consider factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises. For licenses that are combined with 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 for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of progress and related revenue recognition. The measure of progress, and the resulting periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research, development and licensing arrangement. Such a change could have a material impact on the amount of revenue we record in future periods. Under our existing license and collaboration agreements, we have concluded that the transfer of control to the customer occurs over the time period that the research and development services are to be provided by us, and this cost-to-cost method is, in management's judgment, the best measure of progress towards satisfying the performance obligation.

Research and Development Services

The promises under our license and collaboration arrangements often include research and development services to be performed by us on behalf of the partner. Payments or reimbursements resulting from our research and development efforts are estimated at the outset of the arrangement and considered part of the transaction price that is subsequently recognized as revenue because we are the principal in the arrangement for such efforts.

Customer Options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, we evaluate the customer options to determine if they are material rights at the outset of each arrangement. Options to acquire additional goods or services for free or at a discount are deemed to be material rights. If the goods and services underlying the customer options are not determined to be material rights, these customer options are not considered to be performance obligations in the arrangement because they are contingent upon exercise of the option. If the customer options are determined to be a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Milestone Payments

At the inception of each arrangement that includes potential research, development or regulatory milestone payments, we evaluate whether the milestones are considered likely to be met and estimate the amount to be considered for inclusion in the transaction price using the most-likely-amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone payment value is included in the transaction price. For milestone payments due upon events that are not within the control of us or the licensee, such as regulatory approvals, we are not able to assert that it is likely that the regulatory approval will be granted and that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur until those approvals are received. In making this assessment, we evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price of the arrangement. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the amounts of revenue and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments due upon first commercial sales or based on a level of sales, that are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) the occurrence of the related sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue from any of our licensing arrangements.

Information regarding management's judgments and estimates applied in our accounting for our collaboration agreements with Roche in accordance with ASC 606 is summarized below. For additional information, see "—Components of Our Results of Operations—Revenue" and Note 11 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

2017 License and Collaboration Agreement with Roche

In April 2017, we entered into a second license and collaboration agreement with Roche, or the 2017 Roche Agreement, to allow Roche to use our Cell Squeeze technology to enable gene editing of immune cells to discover new targets in cancer immunotherapy. The 2017 Roche Agreement includes several licenses granted by Roche to us and by us to Roche in order to conduct a specified research program in accordance with a specified research plan.

Under the agreement, we received an upfront payment of $5.0 million as a technology access fee and are entitled to (i) payments of up to $1.0 million as reimbursement for our research costs; (ii) milestone payments of up to $7.0 million upon the achievement of specified development milestones; and (iii) annual maintenance fees ranging from $0.5 million to $0.9 million for each year following the fifth anniversary of the effective date, subject to specified prepayment discounts.

In early 2022, all active work streams under the 2017 Roche Agreement were concluded and the agreement was terminated. As of December 31, 2021, we determined that we expected to incur no additional costs to satisfy the remaining performance obligations under the 2017 Roche Agreement and we recognized revenue of $1.2 million under the 2017 Roche Agreement. There was no remaining deferred revenue under the 2017 Roche Agreement as of December 31, 2021.

2018 License and Collaboration Agreement with Roche

In October 2018, we entered into the 2018 Roche Agreement. Under the agreement, Roche was granted option rights to obtain an exclusive license to develop APC products or products derived from the collaboration programs on a product-by-product basis for oncologic indications. These option rights are exercisable upon the achievement of clinical Phase 1 proof of concept and expire, if unexercised, as of a date specified in the agreement. In addition, Roche was granted an option right to obtain an exclusive license to develop a TCL product. This option right is exercisable upon the achievement of clinical proof of concept and expires, if unexercised, as of a date specified in the agreement. For each of the APC products and TCL product, once Roche exercises its option and pays a specified incremental amount ranging from $15.0 million to $50.0 million for APC products and of $100.0 million for the TCL product, Roche will receive worldwide, exclusive commercialization rights for the licensed products, subject to our alternating option to retain U.S. APC commercialization rights. Through December 31, 2022, Roche had not exercised any of its options under the 2018 Roche Agreement.

Under the 2018 Roche Agreement, we received an upfront payment of $45.0 million and are eligible to receive (i) reimbursement of a mid double-digit percentage of our development costs; (ii) aggregate milestone payments on a product-by-product basis of up to $1.6 billion upon the achievement of specified milestones, consisting of up to $217.0 million of development milestone payments, up to $240.0 million of regulatory milestone payments and up to $1.2 billion of sales milestone payments; and (iii) tiered royalties on annual net sales of APC and TCL products licensed under the agreement at specified rates ranging from a mid single-digit percentage to percentage in the low twenties. We received the upfront payment of $45.0 million in October 2018 upon execution of the agreement. In addition, during the second quarter of 2019, we received a payment of $10.0 million following the achievement of the first development milestone under the 2018 Roche Agreement related to submission by us of preclinical data to the FDA, and during the first quarter of 2020, we received a payment of $20.0 million following the achievement of the second development milestone under the 2018 Roche Agreement related to first-patient dosing in a Phase 1 clinical trial.

We assessed our accounting for the 2018 Roche Agreement in accordance with ASC 606 and concluded that Roche is a customer prior to the exercise of any of its options under the agreement. We also identified the following promises under the 2018 Roche Agreement: (i) a non-exclusive license granted to Roche to use our intellectual property and collaboration compounds to conduct research activities related to the research plans under the 2018 Roche Agreement; (ii) specified research and development services related to HPV through Phase 1 clinical trials under a specified research plan; (iii) manufacturing of our SQZ APC platform and equipment in order to support the HPV research plan; (iv) specified research and development services on next-generation APCs under a research plan; (v) specified research and development services on TCL under a research plan; and (vi) participation on a JSC.

We concluded that, in the case of each performance obligation, the license to our intellectual property was not distinct as a result of Roche being unable to benefit from the license on its own or with other resources reasonably available in the marketplace because the license to our intellectual property requires significant specialized capabilities in order to be further developed. We concluded that the license to our intellectual property, research and development activities related to HPV, and manufacturing of our SQZ APC platform and equipment related to HPV were not distinct from each other because the research and manufacturing activities together customize and significantly modify the underlying technology. As such, we determined that each of these related promises under the agreement was not distinct from the others in this group and should be combined into a single performance obligation. We also concluded that the license to our intellectual property and the research and development activities on next-generation APCs were not distinct from each other because the research and development activities customize and significantly modify the underlying technology. As such, we determined that these related promises should be combined into a single performance obligation. Further, we concluded that the license to our intellectual property and the research and development activities on TCL were not distinct from each other because the research and development activities customize and significantly modify the underlying technology. As such, we determined that these related promises should be combined into a single performance obligation. We concluded that the three performance obligations were distinct from each other as they are separate programs and are unrelated. In addition, we determined that the impact of participation on the JSC was insignificant and had an immaterial impact on the accounting model.

Finally, we evaluated the option rights for licenses to develop, manufacture and commercialize the collaboration targets to determine whether these options provide Roche with any material rights for accounting purposes. We concluded that the option exercise prices were not below respective standalone selling prices, and, therefore, the options were marketing offers that do not provide material rights under ASC 606. Accordingly, the options were excluded as performance obligations at the outset of the 2018 Roche Agreement and will be accounted for as separate accounting contracts if and when each option exercise occurs.

Based on these assessments, we identified three performance obligations at the outset of the 2018 Roche Agreement: (1) the license to our intellectual property, the research and development activities related to HPV through Phase 1 clinical trials under a specified research plan, and the manufacturing of our SQZ APC platform and equipment in order to support the HPV research plan, or the first performance obligation; (2) the license to our intellectual property and the research and development activities on next-generation APCs, or the second performance obligation; and (3) the license to our intellectual property and the research and development activities on TCL, or the third performance obligation.

As of entering into the 2018 Roche Agreement, we assessed whether the 2018 Roche Agreement was, for accounting purposes, a modification of the two prior Roche agreements or a separate contract and concluded that it was a modification of the 2015 Roche Agreement. At the termination of the 2015 Roche Agreement, all deliverables were submitted to Roche for review, and as such, we completed all of our obligations under the 2015 Roche Agreement. Because the obligations under the 2015 Roche Agreement were completed at its termination and all arrangement consideration had been recognized as revenue, the accounting treatment as a modification determined by us would result in the same measurement and recognition patterns as would a separate contract. Further, we concluded that the 2018 Roche Agreement was a separate contract from the 2017 Roche Agreement because (i) we contracted to provide distinct goods and services associated with our gene editing platform to discover new targets in cancer immunotherapy, (ii) the 2018 Roche Agreement and 2017 Roche Agreement were not negotiated together as a package with a single commercial objective and (iii) the amount of consideration paid under the 2018 Roche Agreement and 2017 Roche Agreement are not dependent on the price or performance under the other agreement. In addition, we determined that the upfront payment of $45.0 million as well as the reimbursable costs of $10.8 million estimated by us constituted the entirety of the consideration to be included in the transaction price. This transaction price of $55.8 million was initially allocated to the three performance obligations based on the relative standalone

selling price of each obligation. The potential milestone payments that we may be eligible to receive were excluded from the transaction price at the outset of the arrangement because (i) all development and regulatory milestone payments did not meet the criteria for inclusion using the most-likely-amount method and (ii) we recognize as revenue sales-based royalties and milestone payments at the later of the occurrence of the related sales or the date upon which the performance obligation has been satisfied because we believe that the license is the predominant item to which the royalties relate and have applied the sales-based royalty exception. We reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, we will adjust our estimate of the transaction price.

We determined the standalone selling price of each performance obligation under the 2018 Roche Agreement based on our estimate of our costs to be incurred to fulfill the research, development and manufacturing obligations associated with each of the three performance obligations, plus a reasonable margin.

During the fourth quarter of 2019, we evaluated our overall program priorities and determined that in 2020 we would continue to focus our resources on progressing the specified APC programs related to the 2018 Roche Agreement as well as our AAC and TAC platforms. As a result of our continuing focus on these specific programs, we reduced the level of priority of the TCL research activities under the 2018 Roche Agreement and expect to perform such TCL research activities over a longer time period than as originally expected under the research plan of the agreement. Consequently, in the fourth quarter of 2019, we reclassified $5.3 million of our current deferred revenue to non-current deferred revenue in our consolidated balance sheet, and such non-current deferred revenue will remain unrecognized as revenue until TCL research activities resume or the 2018 Roche Agreement is modified by us and Roche. In the fourth quarter of 2022, we determined that based on our internal plans which did not include work on TCL since 2019, and which do not anticipate performing work on TCL in the future prior to the expiration of the option right, as well as Roche's concurrence that no work was performed or expected to be performed in 2023, that we could recognize the remaining deferred revenue of $9.2 million. Accordingly, as of December 31, 2022, there was no deferred revenue associated with the TCL performance obligation.

We separately recognize revenue associated with our performance obligations as the research, development and manufacturing services are provided using an input method, based on the cumulative costs incurred compared to the total estimated costs expected to be incurred to satisfy each performance obligation. The transfer of control to the customer occurs over the time period that the research and development services are to be provided by us, and this cost-to-cost method is, in management’s judgment, the best measure of progress towards satisfying each performance obligation. The amounts received that have not yet been recognized as revenue are deferred as a contract liability in our consolidated balance sheet and will be recognized over the remaining research and development period until each performance obligation is satisfied.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

- vendors in connection with preclinical and clinical development activities;
- CMOs in connection with the process development and scale-up activities and the production of preclinical and clinical trial materials; and
- CROs in connection with clinical trials.

We record the expense and accrual related to contract research and manufacturing based on our estimates of the services received and efforts expended considering a number of factors, including our knowledge of the progress towards completion of the research, development and manufacturing activities; invoicing to date under the contracts; communication from the CMOs, CROs and other companies of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts and purchase orders. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of our common stock for restricted common stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the award for employees and directors and the period during which services are performed for non-employees. We use the straight-line method to record the expense of awards with service-based vesting conditions.

The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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

As of December 31, 2022, we had cash and cash equivalents of $63.7 million, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these balances, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. Our operations may be subject to inflation in the future as a result of the COVID-19 pandemic and its impact on pricing and the supply chain.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Limitations on effectiveness of controls and procedures

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was effective. As an "emerging growth company" as defined in the JOBS Act and a non-accelerated filer, we are not required to comply with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About our Executive Officers and Directors

The following table provides information regarding our executive officers and members of our board of directors (ages as of the date of this Annual Report on Form 10-K):

Name	Age	Position
Howard Bernstein, M.D., Ph.D.	65	Interim Chief Executive Officer and Director
Lawrence Knopf	61	General Counsel
David First	59	Chief People Officer
Richard Capasso	61	Chief Accounting Officer
Marshelle Smith Warren, M.D.	60	Chief Medical Officer
Bernard Coulie, M.D., Ph.D.	56	Chair and Director
Paul Bolno, M.D.	49	Director
Amy. W. Schulman	62	Director
Marc Elia	47	Director
Pushkal Garg, M.D.	55	Director
Klavs F. Jensen, Ph.D.	70	Director
Marc Schegerin, M.D.	47	Director
Sapna Srivastava, Ph.D.	52	Director
Patrick V.J.J. Vink, M.D.	59	Director

Executive Officers

Howard Bernstein, M.D., Ph.D. has served as our Interim Chief Executive Officer since November 2022 and serves as our principal executive officer. He was previously Chief Scientific Officer since June 2015. Prior to joining us, from November 2008 to May 2015, Dr. Bernstein served as the Chief Scientific Officer of Seventh Sense Biosystems, a medical device company. Dr. Bernstein holds an M.D. from Harvard Medical School, a Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology and a Bachelor of Engineering from McGill University. He is a member of the National Academy of Engineering and a Fellow of the American Institute of Medical and Biological Engineering.

Lawrence Knopf has served as our General Counsel since September 2019. Before joining us, from January 2017 to August 2019, Mr. Knopf served as an independent consultant and legal counsel to life science and other business enterprises, on a consulting, project and expert witness basis. Before that, from March 2011 to November 2016, Mr. Knopf served as Senior Vice President and General Counsel at HeartWare International, Inc., a publicly traded medical device company that was acquired by Medtronic in 2016. Mr. Knopf holds a J.D. from the University of Michigan Law School, and a B.S. in accounting and political science from the Wharton School of the University of Pennsylvania.

David First has served as our Chief People Officer since May 2020. Prior to joining us, from September 2018 to May 2020, Mr. First served as the Chief Human Resources Officer of Avedro Inc., a medical technology company that was acquired by Glaukos in 2019. Prior to joining Avedro Inc., Mr. First served as Vice President, Human Resources at Biogen Inc., a global healthcare company. Before that, from June 2015 to November 2017, Mr. First served as Global Head of Human Resources at HeartWare International, Inc., a publicly traded medical device company that was acquired by Medtronic in 2016. Mr. First holds an Master of Arts in Teaching from Union College, and a B.A. in economics from Union College.

Richard Capasso has served as our Chief Accounting Officer since November 2021 and serves as our principal financial and accounting officer. He was previously Vice President, Finance since June 2021. Before joining us, from September 2020 to May 2021, Mr. Capasso was a Senior Director at Danforth Advisors, a firm providing strategic and operational finance and accounting for life science companies. Before that, from October 2015 to June 2020, Mr. Capasso was a Managing Director at Ernst & Young LLP, a multinational professional services firm. Mr. Capasso is a Certified Public Accountant and holds an M.B.A. from the Bentley University, McCallum School of Business and a B.S. from Northeastern University.

Marshelle Smith Warren, M.D. has served as our Chief Medical Officer since June 2022. She was previously Global Development Senior Advisor at Allovir, an allogeneic virus-specific T cell therapy company, from 2019 to 2022. Prior to that, Dr. Warren served Chief Medical Officer and Senior Vice President of R&D at Viracta Therapeutics, an oncology company targeting virus-associated malignancies, from 2016 to 2019. Dr. Warren is board certified in internal medicine and clinical immunology. She received a B.S. in biology from Baylor University and an MD from the University of Nebraska Medical Center College of Medicine. She performed her

residency in internal medicine at St. Joseph's Hospital in Colorado and completed a clinical immunology fellowship at the National Jewish Center for Immunology and Respiratory Medicine.

Directors

Bernard Coulie, M.D., Ph.D., has served as a member of our Board since July 2021 and as our Chair since November 2022. Dr. Coulie has served as Chief Executive Officer and as a Director for Pliant Therapeutics, Inc., a biopharmaceutical company, since February 2016. Prior to joining Pliant, Dr. Coulie cofounded ActoGeniX N.V., a biopharmaceutical company, and held roles of increasing responsibility there, including as Vice President R&D, Chief Medical Officer, and Chief Executive Officer, from September 2006 until February 2015, when it was acquired by Intrexon Corporation. Prior to cofounding ActoGeniX, Dr. Coulie held various positions with increasing responsibilities in drug discovery and clinical development at Johnson & Johnson Pharmaceutical Research and Development Europe. Dr. Coulie previously served as a director of ActoGeniX from April 2010 until February 2015, Biogazelle N.V. from July 2015 until November 2018, Myoscience from June 2016 until March 2019. Dr. Coulie is currently serving as a director and Chairman of Calypso BV. Dr. Coulie holds an M.D. and Ph.D. from the University of Leuven, Belgium and an MBA from the Vlerick Management School, Leuven, Belgium. We believe that Dr. Coulie's experience in the biotechnology industry and executive leadership at various biopharmaceutical companies qualify him to serve on our Board.

Amy W. Schulman has served as a member of our Board and served as our Chair from June 2015 to October 2022. In July 2015, Ms. Schulman co-founded Lyndra Therapeutics, Inc., a pharmaceutical company, served as its Chief Executive Officer until February 2017 and as of September 2019 serves as Executive Chair. In addition, from August 2014 to November 2016, Ms. Schulman served as Chief Executive Officer of Arsia Therapeutics, Inc., a pharmaceutical company, until Arsia was acquired by Eagle Pharmaceuticals, Inc., a pharmaceutical company. Ms. Schulman joined Polaris Partners in August 2014 and became a Managing Partner in 2019. Since July 2014, Ms. Schulman has served as a senior lecturer at Harvard Business School. From January 2019 until January 2021, Ms. Schulman served as a director of Cyclerion Therapeutics, Inc. and currently serves as a director of Alnylam Pharmaceuticals, Inc. and on the Mount Sinai Hospital Board of Trustees. Ms. Schulman holds a J.D. from Yale Law School as well as B.A. degrees in Philosophy and English from Wesleyan University. We believe Ms. Schulman's extensive industry experience qualifies her to serve on our Board.

Paul B. Bolno, M.D. has served on our Board since June 2020. Since December 2013, Dr. Bolno has served as the President and Chief Executive Officer of Wave Life Sciences Ltd., a genetic medicines company, and has served as a director of Wave Life Sciences Ltd. since April 2014. Prior to joining Wave, Dr. Bolno served at GlaxoSmithKline, a pharmaceutical company, from 2009 to 2013 in various roles, including Vice President, Worldwide Business Development—Head of Asia BD and Investments, Head of Global Neuroscience BD, a director of Glaxo Welcome Manufacturing, Pte. Ltd. in Singapore and Vice President, Business Development for the Oncology Business Unit, where he helped establish GlaxoSmithKline's global oncology business and served as a member of the Oncology Executive Team, Oncology Commercial Board and Cancer Research Executive Team. Prior to GlaxoSmithKline, Dr. Bolno served as Director of Research at Two River LLC, a health care private equity firm, from 2004 to 2009. Dr. Bolno earned a medical degree from MCP-Hahnemann School of Medicine and an M.B.A. from Drexel University. He was a general surgery resident and cardiothoracic surgery postdoctoral research fellow at Drexel University College of Medicine. We believe that Dr. Bolno's experience in the biotechnology industry and leading a biopharmaceutical company qualify him to serve on our Board.

Marc Elia has served as a member of our Board since May 2018. In September 2019, Mr. Elia founded M28 Capital, a healthcare sector investment fund. Prior to that, from January 2012 to September 2019, Mr. Elia served as a partner at Bridger Capital, an investment fund. Mr. Elia holds a B.A. in Economics from Carleton College. We believe that Mr. Elia's broad operational and transactional experience qualify him to serve on our Board.

Pushkal Garg, M.D. has served as a member of our Board since August 2018. Dr. Garg currently serves as Chief Medical Officer and Executive Vice President at Alnylam Pharmaceuticals, Inc., a biopharmaceutical company focused on the discovery, development, and commercialization of RNA interference therapeutics. Prior to joining Alnylam in October 2014, he held clinical development leadership roles at Bristol-Myers Squibb Corporation and Millennium Pharmaceuticals. Before joining the biopharmaceutical industry, he was on the faculty at Harvard Medical School and the Brigham and Women's Hospital in Boston. Dr. Garg holds an M.D. from the University of California, San Francisco, School of Medicine, where he also completed a residency in Internal Medicine, and an A.B. in Biochemistry from the University of California, Berkeley. We believe Dr. Garg's extensive medical and scientific knowledge and industry experience qualify him to serve on our Board.

Klavs F. Jensen, Ph.D. has served as a member of our Board since March 2013 and was a co-founder of our company. Since 1989, Dr. Jensen has served as Professor of Chemical Engineering and of Materials Science and Engineering at the Massachusetts Institute of Technology. From 2007 to 2015, Dr. Jensen served as Department Head for Chemical Engineering. Dr. Jensen was a member of the Board of Technical University of Denmark from 2009 to 2016. Dr. Jensen holds a Ph.D. in Chemical Engineering from the University of Wisconsin and an M.S. in Chemical Engineering from Technical University of Denmark. He is a member of the U.S. Academies of

Engineering and Science. We believe Dr. Jensen's pioneering academic work, extensive medical and scientific knowledge and industry experience qualify him to serve on our Board.

Marc Schegerin, M.D. has served as a member of our Board since October 2020. Since April 2020, Dr. Schegerin has served as the Chief Financial Officer and Chief Operating Officer at Morphic Therapeutic, Inc., a biopharmaceutical company. From April 2018 to January 2020, Dr. Schegerin served as Chief Financial Officer, Treasurer and Head of Strategy & Communications at ArQule, an oncology-focused drug developer, until its acquisition by Merck & Co. in January 2020. Prior to this role, Dr. Schegerin served as a Director at Citigroup, from June 2016 to April 2018. Dr. Schegerin earned his M.D. from Dartmouth Medical School and M.B.A. from the Tuck School of Business at Dartmouth and undergraduate degrees in premedical studies from Harvard University and finance from Tulane University. We believe Dr. Schegerin's broad operational and transactional experience qualify him to serve on our Board.

Sapna Srivastava, Ph.D. has served as a member of our Board since October 2020. Dr. Srivastava served as the Interim Chief Financial Officer of eGenesis, Inc. from March 2021 to October 2021. From September 2017 to January 2019, Dr. Srivastava served as the Chief Financial and Strategy Officer at Abide Therapeutics, Inc., a biopharmaceutical company that was acquired by H. Lundbeck A/S in 2019. From April 2015 to December 2016, Dr. Srivastava served as the Chief Financial and Strategy Officer at Intellia Therapeutics, Inc., a genome editing company. Dr. Srivastava currently serves as a director of private company Asclepix Therapeutics, Inc. and multiple public companies, which are Talaris Therapeutics, Inc., Aura Biosciences, Nuvalent Inc, and Social Capital Suvretta Holdings Corp II . She also served as a director of VelosBio Inc. from October 2020 to December 2020. Dr. Srivastava holds a Ph.D. from N.Y.U. University School of Medicine and a B.S. from St. Xavier's College, University of Bombay. We believe Dr. Srivastava's broad financial, operational, and transactional experience qualify her to serve on our Board.

Patrick V.J.J. Vink, M.D. has served as a member of our Board since July 2021. He has significant experience as a senior executive, having worked in the pharmaceutical industry for more than 30 years. Since May 2020, Dr. Vink has served as Chairman at BiognoSys AG, a privately held proteomics company in Switzerland. Since June 2016, Dr. Vink has also served as Chairman of venture capital-backed NMD Pharma, a neurology biopharmaceutical company in Denmark and F2G Ltd, a rare fungal disease UK and Austria based company. In addition, Dr. Vink is a board member at Amryt Pharma PLC, Santhera AG and Spero Therapeutics, Inc. and in 2019 began working with Athyrium as a Senior Advisor. While serving in these capacities, Dr. Vink has been involved in initial public listings and geographic expansions and has contributed to the achievement of significant development and commercial milestones. Earlier in his career he held several leadership positions across the industry, including Head of Global Biopharmaceuticals for the Sandoz division of the Novartis Group, Vice President International Business for Biogen Inc., and Head of Worldwide Marketing, Cardiovascular and Thrombosis at Sanofi-Synthelabo Ltd. Dr. Vink also served as a member of the Executive Committee of the European Federation of Pharmaceutical Industries and Associations from 2013 to 2015. Dr. Vink graduated as a medical doctor from the University of Leiden, Netherlands in 1988 and obtained his Masters of Business Administration in 1992 at the University of Rochester. We believe Dr. Vink's broad experience and leadership positions in the industry qualify him to serve on our Board.

Code of Ethics

We have 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. We have posted a current copy of the Code of Business Conduct and Ethics on our website, *www.sqzbiotech.com*, in the "Investors and Media" section under "Governance." In addition, we intend to post on our website all disclosures that are required by law or the rules of the NYSE concerning any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics.

The remainder of the response to this Item 10 will be included in our definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The table below sets forth the number of securities to be issued upon exercise of outstanding options, warrants and rights as of December 31, 2022.

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	Number of Securities Available for Future Issuance under Equity Compensation Plans (excludes securities reflected in first column) (2)
Equity compensation plans approved by security holders (1)	5,358,310	$ 8.09	3,768,310
Equity compensation plans not approved by security holders	—	—	—
Total	5,358,310	$ 8.09	3,768,310

(1) Consists of the SQZ Biotechnologies Company 2020 Incentive Award Plan, or the 2020 Plan and the SQZ Biotechnologies Company 2020 Employee Stock Purchase Plan, or the ESPP.

(2) Consists of 3,058,628 shares available for future issuance under the 2020 Plan and 709,682 shares available for future issuance under the ESPP. The 2020 Plan provides for an annual increase on the first day of each calendar year beginning on January 1, 2021 and ending on January 1, 2030, by an amount equal to the lesser of (A) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our Board. The number of shares authorized under our ESPP will increase on the first day of each calendar year beginning on January 1, 2021 and ending on and including January 1, 2030, by an amount equal to the lesser of (A) 1% of the shares of Common Stock outstanding as of the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Common Stock as determined by our Board; provided, however, that no more than 3,724,461 shares of Common Stock may be issued under the ESPP.

The remainder of the response to this Item 12 will be included in our definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(a)(2) All financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Restated Certificate of Incorporation of SQZ Biotechnologies Company	8-K	001-39662	3.1	11/04/2020	
3.2	Amended and Restated Bylaws of SQZ Biotechnologies Company	S-1/A	333-249422	3.4	10/26/2020	
4.1	Amended and Restated Investors' Rights Agreement, dated as of December 19, 2019, as amended	S-1	333-252889	4.1	02/09/2021	
4.2	Specimen Stock Certificate	S-1/A	333-249422	4.2	10/26/2020	
4.3	Description of Securities	10-K	001-39662	4.3	03/18/2021	
10.1#	2014 Stock Incentive Plan, as amended, and form of agreements thereunder	S-8	333-249774	99.1	10/30/2020	
10.2#	2020 Incentive Award Plan and form of agreements thereunder	S-8	333-249774	99.2	10/30/2020	
10.3#	Amended Non-Employee Director Compensation Program	10-K	001-39662	10.3	03/16/2022	
10.4#	2020 Employee Stock Purchase Plan	S-8	333-249774	99.3	10/30/2020	
10.5#	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-249422	10.5	10/26/2020	
10.6	Lease between the Registrant and Arsenal Yards Holding LLC, dated December 11, 2018	S-1/A	333-249422	10.6	10/26/2020	
10.7†	License and Collaboration Agreement among Registrant, F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., effective as of October 5, 2018	S-1	333-249422	10.7	10/09/2020	
10.8†	Accord relating to License and Collaboration Agreement among Registrant, F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., effective as of November 5, 2019	S-1	333-249422	10.8	10/09/2020	
10.9†	Amended and Restated Exclusive Patent License Agreement, dated as of December 1, 2015, by and between the Registrant and Massachusetts Institute of Technology	S-1	333-249422	10.9	10/09/2020	
10.10#	Employment Agreement between the Registrant and Marshelle Smith Warren, M.D, dated June 1, 2022	10-Q	001-39662	10.1	08/04/2022	

10.11#	Employment Agreement between the Registrant and Micah Zajic, dated July 7, 2022	8-K	001-39662	10.1	07/11/2022	
10.12#	Employment Agreement between the Registrant and Armon Sharei, Ph.D., dated October 23, 2020	S-1/A	333-249422	10.14	10/26/2020	
10.13#	Employment Agreement between the Registrant and Lawrence Knopf, dated October 29, 2020	S-1	333-252889	10.15	02/09/2021	
10.14#	Employment Agreement between the Registrant and David First, dated October 29, 2020	10-K	001-39662	10.11	03/16/2022	
10.15#	Separation Agreement between the Registrant and Armon Sharei, dated November 30, 2022					*
10.16#	Separation Agreement between the Registrant and Micah Zajic. dated November 28, 2022					*
10.17#	Employment Agreement between the Registrant and Howard Bernstein, Ph.D., dated November 28, 2022					*
21.1	Subsidiaries of the Registrant					*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
101.INS	Inline XBRL Instance Document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*

104	Cover Page Interactive Data File (embedded within the Inline XBRL)	*

* Filed herewith.
** Furnished herewith.
# Indicates management contract or compensatory plan.
† Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

SQZ Biotechnologies Company

Date: March 22, 2023

By: /s/ Howard Bernstein Ph.D.
Howard Bernstein, Ph.D.
Interim Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Howard Bernstein, Ph.D. **Howard Bernstein, Ph.D.**	Interim Chief Executive Officer and Director (principal executive officer)	March 22, 2023
/s/ Richard Capasso **Richard Capasso**	Chief Accounting Officer (principal financial and accounting officer)	March 22, 2023
/s/ Bernard Coulie, M.D., Ph.D. **Bernard Coulie, M.D., Ph.D.**	Chair and Director	March 22, 2023
/s/ Paul Bolno, M.D. **Paul Bolno, M.D.**	Director	March 22, 2023
/s/ Amy W. Schulman **Amy W. Schulman**	Director	March 22, 2023
/s/ Marc Elia **Marc Elia**	Director	March 22, 2023
/s/ Pushkal Garg, M.D. **Pushkal Garg, M.D.**	Director	March 22, 2023
/s/ Klavs F. Jensen, Ph.D. **Klavs F. Jensen, Ph.D.**	Director	March 22, 2023
/s/ Marc Schegerin, M.D. **Marc Schegerin, M.D.**	Director	March 22, 2023
/s/ Sapna Srivastava, Ph.D. **Sapna Srivastava, Ph.D.**	Director	March 22, 2023
/s/ Patrick V.J.J. Vink, M.D. **Patrick V.J.J. Vink, M.D.**	Director	March 22, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of SQZ Biotechnologies Company

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SQZ Biotechnologies Company and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 22, 2023

We have served as the Company's auditor since 2019.

SQZ BIOTECHNOLOGIES COMPANY

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	DECEMBER 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 63,709	$ 143,513
Accounts receivable	—	3,000
Prepaid expenses and other current assets	4,495	4,122
Total current assets	68,204	150,635
Property and equipment, net	1,959	3,046
Restricted cash	2,305	2,305
Other assets	—	323
Operating lease right-of-use assets	27,432	69,843
Total assets	$ 99,900	$ 226,152
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,511	$ 3,971
Accrued expenses	8,893	6,810
Accrued restructuring expenses	3,162	—
Current portion of deferred revenue	715	12,507
Current portion of operating lease liabilities	6,562	9,936
Total current liabilities	21,843	33,224
Deferred revenue, net of current portion	—	9,196
Operating lease liabilities, net of current portion	20,909	59,756
Total liabilities	42,752	102,176
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021, respectively; No shares issued or outstanding.	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021, respectively; 29,491,125 and 28,133,368 shares issued and outstanding at December 31, 2022 and 2021, respectively.	29	28
Additional paid-in capital	332,093	319,458
Accumulated deficit	(274,974)	(195,510)
Total stockholders' equity	57,148	123,976
Total liabilities and stockholders' equity	$ 99,900	$ 226,152

The accompanying notes are an integral part of these consolidated financial statements.

SQZ BIOTECHNOLOGIES COMPANY

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	YEAR ENDED DECEMBER 31,	
	2022	2021
Collaboration revenue	$ 21,029	$ 27,098
Grant revenue	449	—
Total revenue	21,478	27,098
Operating expenses:		
Research and development	70,984	70,148
General and administrative	26,319	25,719
Restructuring charges	4,859	—
Total operating expenses	102,162	95,867
Loss from operations	(80,684)	(68,769)
Other income (expense):		
Interest income	1,223	36
Other expense, net	(3)	(8)
Total other income, net	1,220	28
Net loss and comprehensive loss	(79,464)	(68,741)
Net loss per share, basic and diluted	$ (2.76)	$ (2.49)
Weighted-average common shares outstanding, basic and diluted	28,812,904	27,578,844

The accompanying notes are an integral part of these consolidated financial statements.

SQZ BIOTECHNOLOGIES COMPANY

Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT			
Balances at December 31, 2020	24,786,324	$ 25	$ 253,943	$ (126,769)	$ 127,199
Issuance of common stock upon public offering, net of issuance costs of $798	3,000,000	3	55,599	—	55,602
Issuance of common stock upon exercise of stock options	333,417	—	1,307	—	1,307
Issuance of common stock under employee stock purchase plan	13,627	—	104	—	104
Stock-based compensation expense	—	—	8,505	—	8,505
Net loss	—	—	—	(68,741)	(68,741)
Balances at December 31, 2021	28,133,368	28	319,458	(195,510)	123,976
Issuance of common stock under at-the-market offering, net of issuance costs of $197	1,261,226	1	4,066	—	4,067
Issuance of common stock upon exercise of stock options	14,757	—	29	—	29
Issuance of common stock under employee stock purchase plan	81,774	—	137	—	137
Stock-based compensation expense	—	—	8,403	—	8,403
Net loss	—	—	—	(79,464)	(79,464)
Balances at December 31, 2022	29,491,125	$ 29	$ 332,093	$ (274,974)	$ 57,148

The accompanying notes are an integral part of these consolidated financial statements.

SQZ BIOTECHNOLOGIES COMPANY

Consolidated Statements of Cash Flows
(In thousands)

	YEAR ENDED DECEMBER 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (79,464)	$ (68,741)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,504	1,208
Amortization of operating lease right-of-use assets	10,180	9,822
Stock-based compensation expense	8,403	8,505
Loss on disposal of property and equipment	33	7
Changes in operating assets and liabilities:		
Accounts receivable	3,000	(1,108)
Prepaid expenses and other current assets	(373)	460
Accounts payable	(1,422)	1,074
Accrued expenses	2,083	(283)
Accrued restructuring expenses	3,162	—
Deferred revenue	(20,988)	(23,873)
Other assets	323	(323)
Operating lease liabilities	(9,990)	(8,710)
Other liabilities	—	(175)
Net cash used in operating activities	(83,549)	(82,137)
Cash flows from investing activities:		
Purchases of property and equipment	(522)	(613)
Proceeds from sale of equipment	34	—
Net cash used in investing activities	(488)	(613)
Cash flows from financing activities:		
Proceeds from issuance of common stock under at-the market offering of common stock, net of issuance costs	4,067	—
Proceeds from follow-on public offering of common stock, net of issuance costs	—	56,400
Payment of public offering costs	—	(1,904)
Proceeds from issuance of common stock under employee stock purchase plan	29	103
Proceeds from exercise of stock options	137	1,307
Net cash provided by financing activities	4,233	55,906
Net (decrease) increase in cash, cash equivalents and restricted cash	(79,804)	(26,844)
Cash, cash equivalents and restricted cash at beginning of period	145,818	172,662
Cash, cash equivalents and restricted cash at end of period	$ 66,014	$ 145,818
Supplemental disclosure of non-cash investing and financing activities:		
Lease assets obtained in exchange for operating lease liabilities	$ —	$ 31,307
Reduction in lease assets and liabilities due to lease amendment	$ (32,230)	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business and Basis of Presentation

SQZ Biotechnologies Company (the "Company") is a clinical-stage biotechnology company developing cell therapies for patients with cancer and other serious medical conditions. The Company uses its proprietary technology, Cell Squeeze, to physically squeeze cells through a microfluidic chip, temporarily opening the cell membrane and enabling biologic material of interest, or cargo, to diffuse into the cell. The Company is using Cell Squeeze to create multiple cell therapy platforms focused on directing specific immune responses. The Company was incorporated in March 2013 under the laws of the State of Delaware.

The Company is subject to a number of risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, the ability to obtain additional financing, protection of proprietary technology, dependence on key personnel, the ability to attract and retain qualified employees, compliance with government regulations, the impact of the COVID-19 coronavirus, and the clinical and commercial success of its product candidates. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On February 17, 2021, the Company completed a follow-on public offering (the "Follow-On Offering") pursuant to which it issued and sold 3,000,000 shares of its common stock. The aggregate proceeds, net of commissions and underwriting discounts received by the Company from the Follow-On Offering were approximately $56.4 million, before deducting offering costs payable by the Company, which were $0.8 million.

On November 10, 2021, the Company entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") to issue and sell up to $75,000,000 in shares of the Company's common stock from time to time during the term of the Sales Agreement through an "at-the-market" equity offering program under which Jefferies acts as the Company's sales agent (the "ATM Facility"). During the year ended December 31, 2022, the Company sold 1,261,226 shares of common stock under the ATM Facility for net proceeds of approximately $4.1 million.

Going Concern Assessment

Management has assessed the Company's ability to continue as a going concern in accordance with the requirements of ASC 205-40, taking into consideration its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future and the need to raise additional capital to finance future operations. Through December 31, 2022, the Company has funded its operations primarily with proceeds from sales of convertible preferred stock, payments received in connection with collaboration agreements, proceeds from borrowings under a convertible promissory note, which converted into shares of convertible preferred stock, and more recently the proceeds from its IPO, the Follow-On Offering and the ATM Facility. The Company has incurred recurring losses since inception, including a net loss of $79.5 million for the year ended December 31, 2022. As of December 31, 2022, the Company had an accumulated deficit of $275.0 million. Based on its current cash expenditure forecast, the Company expects that its existing cash and cash equivalents will fund its operations into the first quarter of 2024.

The Company expects to continue to generate operating losses in the foreseeable future. As of March 22, 2023, the issuance date of the annual consolidated financial statements for the year ended December 31, 2022, the Company has concluded that there is substantial doubt about its ability to continue as a going concern for a period of one year from the date that these consolidated financial statements are issued. The Company will require additional funding through private or public equity financings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. If the Company is unable to obtain funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, or at all.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going

concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Impact of the COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was initially reported and since then, COVID-19 has spread globally. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on hospitals, businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, prices have increased, and the use of facilities and production have been suspended. The future progression of the pandemic and its effects on the Company's business and operations are uncertain.

The COVID-19 pandemic has impacted and may continue to impact personnel at third-party manufacturing facilities or the availability or cost of materials, which would disrupt the Company's supply chain. It also has affected and may continue to affect the Company's ability to enroll patients in and timely complete its ongoing clinical trials of SQZ-eAPC-HPV and SQZ-AAC-HPV and delay the initiation of future clinical trials, disrupt regulatory activities or have other adverse effects on its business and operations.

The Company is monitoring the potential impact of the COVID-19 pandemic and general economic conditions on its business and financial statements. To date, the Company has not incurred impairment losses in the carrying values of its assets as a result of the pandemic and it is not aware of any specific related event or circumstance that would require it to revise its estimates reflected in these consolidated financial statements. The extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations, financial condition and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

Basis of Presentation

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

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, SQZ Biotechnologies Security Corporation, SQZ Biotech HK Limited and SQZ Biotech (Shanghai) Co. Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses, the valuation of common stock and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of accounts receivable and cash and cash equivalents. The Company's cash and cash equivalents and restricted cash are maintained in bank deposit accounts and money market funds that regularly exceed federally insured limits. The Company is exposed to credit risk on its cash, cash equivalents and restricted cash in the event of default by the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation ("FDIC"). As of December 31, 2021, all of the Company's accounts receivable were related to its collaboration agreements with Roche (see Note 11).

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and to process its product candidates for its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process or supply chain.

Cash Equivalents

The Company considers all highly liquid investments in marketable securities with original maturities of three months or fewer at the date of purchase to be cash equivalents.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering in stockholder's equity as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss.

Deferred offering costs as of December 31, 2021 were expenses directly related to the Form S-3 filed with the SEC on November 12, 2021 and declared effective on November 18, 2021 (the "Shelf Registration"). These costs consist of legal, accounting, printing and filing fees that the Company has capitalized, including fees incurred by the independent registered public accounting firm directly related to the Shelf Registration. Deferred costs associated with the Shelf Registration are reclassified to additional paid in capital on a pro-rata basis when the Company completes offerings under the Shelf Registration, with any remaining deferred offering costs to be charged to the results of operations if the planned offering is abandoned, or at the end of the three-year life of the Shelf Registration. The Company had $0 and $0.3 million of deferred offering costs as of December 31, 2022 and 2021, respectively.

Accounts Receivable Allowance

Accounts receivable are presented net of an allowance for doubtful accounts, which is an estimate of amounts that may not be collectible. The Company performs ongoing evaluations of its accounts receivable and, if necessary, provides an allowance for doubtful accounts and expected losses. The Company writes off accounts receivable against the allowance when it determines a balance is uncollectible and no longer actively pursues collection of the receivable.

As of December 31, 2022 and 2021, the Company had no allowance for doubtful accounts. During the years ended December 31, 2022 and 2021 the Company did not record any provisions for doubtful accounts and did not write off any accounts receivable balances.

Restricted Cash

As of December 31, 2022 and 2021, the Company maintained letters of credit totaling $2.3 million for the benefit of the landlord of its leased properties. The Company was required to maintain separate cash balances of $2.3 million to secure the letters of credit. The Company classified these separate cash balances of $2.3 million as restricted cash (non-current) in the consolidated balance sheets as of December 31, 2022 and 2021 based on the release dates of the restrictions on this cash. As of December 31, 2022 and 2021, the cash, cash equivalents and restricted cash of $66.0 million and $145.8 million, respectively, presented in the consolidated statements of cash flows included cash and cash equivalents of $63.7 million and $143.5 million, respectively, and restricted cash of $2.3 million for each of the years ended December 31, 2022 and 2021.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	ESTIMATED USEFUL LIFE
Machinery and equipment	3 to 5 years
Furniture and fixtures	7 years
Leasehold improvements	Shorter of term of lease or 7 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company continually evaluates long-lived assets for potential impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares the carrying values of the asset group to the expected future undiscounted cash flows that the asset group is expected to generate from the use and eventual disposition of the long-lived asset group. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. If such

asset group is considered to be impaired, the impairment loss to be recognized would be based on the excess of the carrying value of the impaired asset group over its fair value. The Company did not recognize any impairment losses on long-lived assets during the years ended December 31, 2022 and 2021.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The fair value of the Company's cash equivalents are determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts receivable, unbilled receivables, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Leases

The Company accounts for leases under Accounting Standards Codification ("ASC") 842, *Leases* ("ASC 842"). The Company has operating leases for office space as well as a contract for manufacturing under which the Company has a dedicated suite. The Company may enter into similar arrangements in the future. Under ASC 842, the Company determines whether such arrangements contain a lease at the inception of a contract by assessing whether there is an identified asset and whether a contract conveys the right to control the use of the identified asset in exchange for consideration and the right to obtain the economic benefits from the use of the identified asset.

Upon commencement of an identified lease, the Company records a right-of-use asset, which represents the Company's right to use the underlying asset for the lease term, and records a lease liability, which represents the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at commencement date of the lease based on the present value of the future minimum lease payments over the lease term. Lease payments are discounted at the lease commencement date using the rate implicit in the lease, unless that rate is not readily determinable. As most of the Company's leases do not provide an implicit rate, the Company determines an incremental borrowing rate, which represents an internally estimated rate that would be incurred by the Company to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment, based on the information available at the commencement date of each lease in determining the present value of the future minimum lease payments. The determination of the incremental borrowing rate is a significant management judgment, which is based on an analysis that includes the credit rating of the Company, geographical risk, and U.S. Treasury and corporate bond yields.

After lease commencement and the establishment of a right-of-use asset and operating lease liability, lease expense is recorded on a straight-line basis over the lease term. As permitted by ASC 842, leases with an initial term of 12 months or fewer are not recorded in the consolidated balance sheets.

The Company often enters into contracts that contain both lease and non-lease components. Non-lease components include real estate taxes, insurance, maintenance, utilities and other operating costs. The Company combines the lease and non-lease components of fixed costs in its lease arrangements as a single component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

The Company's lease terms often include renewal options. The amounts determined for the Company's right-of-use assets and lease liabilities generally do not assume that any renewal options or any early-termination provisions, if any, are exercised, unless it is reasonably certain that the Company will exercise such options.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is developing methods of engineering cell function and therapies for the treatment of patients across a range of indications. The Company has determined that its chief operating decision maker is its Chief Executive Officer. The Company's chief operating decision maker reviews the Company's financial information on a consolidated basis for purposes of allocating resources and assessing financial performance.

All of the Company's tangible assets are held in the United States, and all of the Company's collaboration revenue is derived from its collaboration partner headquartered in Switzerland.

Revenue Recognition for License and Collaboration Arrangements

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs 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 in the contract; and (v) recognize revenue when, or as, the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company 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 each contract, determines which goods or services are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, that performance obligation is satisfied.

The Company enters into licensing arrangements that are within the scope of ASC 606, under which it may exclusively license to third parties rights to research, develop, manufacture and commercialize its product candidates. The terms of these arrangements typically include payment to the Company of one or more of the following: nonrefundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and sales milestone payments; and royalties on net sales of licensed products. The payment terms under the Company's existing licensing arrangements are 60 days.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its arrangements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the assessment of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company also uses judgment to determine whether milestone payments or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price, as described below. The transaction price is allocated to each performance obligation based on the relative standalone selling price of each performance obligation in the contract, and the Company recognizes revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. Management estimates the standalone selling price of each of the identified performance obligations in the Company's customer contracts, maximizing the use of observable inputs. Because the Company has not sold the same goods or services in its contracts separately to any customers on a standalone basis and there are no similar observable transactions in the marketplace, the Company estimates the standalone selling price of each performance obligation in its customer arrangements based on its estimate of costs to be incurred to fulfil its obligations associated with the performance, plus a reasonable margin.

The Company has determined that its only contract liability under ASC 606 is deferred revenue. Amounts received prior to revenue recognition are recorded as deferred revenue in the consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion, in the consolidated balance sheets.

Exclusive Licenses

If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from nonrefundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or

performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises. For licenses that are combined 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. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. The measure of progress, and the resulting periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research, development and licensing arrangement. Such a change could have a material impact on the amount of revenue the Company records in future periods. Under the Company's existing license and collaboration agreements, the Company has concluded that the transfer of control to the customer occurs over the time period that the research and development services are to be provided by the Company, and this cost-to-cost method is, in management's judgment, the best measure of progress towards satisfying the performance obligation.

Research and Development Services

The promises under the Company's license and collaboration arrangements often include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are estimated at the outset of the arrangement and considered part of the transaction price that is subsequently recognized as revenue because the Company is the principal in the arrangement for such efforts.

Customer Options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the Company evaluates the customer options to determine if they are material rights at the outset of each arrangement. Options to acquire additional goods or services for free or at a discount are deemed to be material rights. If the goods and services underlying the customer options are not determined to be material rights, these customer options are not considered to be performance obligations in the arrangement because they are contingent upon exercise of the option. If the customer options are determined to be a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Milestone Payments

At the inception of each arrangement that includes potential research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered likely to be met and estimates the amount to be considered for inclusion in the transaction price using the most-likely-amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone payment value is included in the transaction price. For milestone payments due upon events that are not within the control of the Company or the licensee, such as regulatory approvals, the Company is not able to assert that it is likely that the regulatory approval will be granted and that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur until those approvals are received. In making this assessment, the Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price of the arrangement. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the amounts of revenue and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments due upon first commercial sales or based on a level of sales, that are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) the occurrence of the related sales or (ii) the date upon which 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 recognized any royalty revenue from any of its licensing arrangements.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials, as well as the costs of licensing technology and costs related to collaboration arrangements.

Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Research and Manufacturing Contract Costs and Accruals

The Company has entered into various research, development and manufacturing contracts with research institutions and other companies in the United States. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research, development and manufacturing costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the research, development and manufacturing activities, invoicing to date under the contracts, communication from the research institutions and other companies of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs.

Restructuring Charges

Restructuring charges include costs directly associated with exit or disposal activities. Such costs may include employee salary continuance, severance, termination benefits, contract termination fees and penalties, and other exit or disposal costs. In general, the Company records involuntary employee-related exit and disposal costs when management has the authority to commit to a restructuring plan, there is a substantive plan for employee severance, there has been a communication to impacted personnel and related costs are probable and estimable. For one-time termination benefits (i.e., no substantive plan) and employee retention costs, expense is recorded when the employees are entitled to receive such benefits and the amount can be reasonably estimated. Contract termination fees and penalties and other exit and disposal costs are generally recorded when incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

For stock-based awards granted to non-employees, employees and directors, the Company estimates the grant-date fair value of each award using the Black-Scholes option-pricing model. Compensation expense for these awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

The Company accounts for forfeitures of stock-based awards as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense.

The Company classifies stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2022 and 2021, there were no changes in stockholders' equity that resulted from transactions or economic events other than with stockholders.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents. The Company reported a net loss for each of the years ended December 31, 2022 and 2021.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves (i.e., unrecognized tax benefits) that are considered appropriate as well as the related net interest.

Recently Issued Accounting Pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in the earlier recognition of credit losses, if any. In May 2019, the FASB issued ASU No. 2019-05, Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief ("ASU 2019-05"), which provides additional implementation guidance on the previously issued ASU 2016-13. For the Company, both ASU 2016-13 and ASU 2019-05 are effective for fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact that the adoption of ASU 2016-13 will have on its consolidated financial statements, however the Company does not expect that the standard will have a material impact on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-18"). ASU 2018-18 makes targeted improvements to GAAP for collaborative arrangements, including (i) clarification that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account, (ii) adding unit-of-

account guidance in ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 and (iii) a requirement that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer. For the Company, this guidance was effective for fiscal years beginning after December 15, 2020. The Company adopted ASU 2018-18 as of January 1, 2021 and the standard did not have an impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740) ("ASU 2019-12"), which simplifies the accounting for income taxes by eliminating certain exceptions, including the approach for intraperiod tax allocation, the accounting for income taxes in an interim period, hybrid taxes and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. The Company adopted this standard as of January 1, 2022 and the standard did not have a material impact on its consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10, Disclosures by Business Entities about Government Assistance, which requires business entities to provide certain disclosures when they have 1) received government assistance and 2) use a grant or contribution accounting model by analogy to other accounting guidance. The Company adopted this standard as of January 1, 2022 and the standard did not have a material impact on its consolidated financial statements.

3. Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	FAIR VALUE MEASUREMENTS AT DECEMBER 31, 2022 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Cash equivalents:				
Money market funds	$ 62,598	$ —	$ —	$ 62,598
	$ 62,598	$ —	$ —	$ 62,598

	FAIR VALUE MEASUREMENTS AT DECEMBER 31, 2021 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Cash equivalents:				
Money market funds	$ 142,547	$ —	$ —	$ 142,547
	$ 142,547	$ —	$ —	$ 142,547

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no changes to the valuation methods during the years ended December 31, 2022 and 2021. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1 or Level 2 during the years ended December 31, 2022 and 2021.

4. Prepaid Expenses and Other Current Assets

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

	DECEMBER 31,	
	2022	2021
Prepaid expenses	$ 4,111	$ 4,027
Other receivables	384	95
	$ 4,495	$ 4,122

5. Property and Equipment, Net

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

	DECEMBER 31,	
	2022	2021
Machinery and equipment	$ 6,840	$ 6,659
Leasehold improvements	579	579
Furniture and fixtures	319	319
	7,738	7,557
Less: Accumulated depreciation and amortization	(5,779)	(4,511)
	$ 1,959	$ 3,046

Depreciation and amortization expense was $1.5 million and $1.2 million for the years ended December 31, 2022 and 2021, respectively. In addition to the depreciation and amortization expense recorded during the year ended December 31, 2022, the Company recorded restructuring charges of $0.4 million (see Note 13) which increased the accumulated depreciation on laboratory equipment that is no longer required and will be disposed of.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	DECEMBER 31,	
	2022	2021
Accrued external research, development and manufacturing costs	$ 5,264	$ 2,156
Accrued employee compensation and benefits	2,578	3,040
Other	1,051	1,614
	$ 8,893	$ 6,810

7. Stock-Based Compensation

On October 20, 2020, the Company's board of directors adopted, and on October 22, 2020 its stockholders approved, the 2020 Incentive Award Plan (the "2020 Plan"). The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the 2020 Plan is subject to an annual increase on the first day of each calendar year, beginning on January 1, 2021 and ending on and including January 1, 2030, equal to the lesser of (i) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by the board of directors. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2020 Plan are added back to the shares of common stock available for issuance under the 2020 Plan. As of December 31, 2022, there were 3,058,628 shares available for future issuance under the 2020 Plan.

On October 20, 2020, the Company's board of directors adopted, and on October 22, 2020 its stockholders approved, the 2020 Employee Stock Purchase Plan (the ''2020 ESPP''). The number of shares of common stock that may be issued under the 2020 ESPP automatically increases on the first day of each calendar year, beginning on January 1, 2021 and ending on and including January 1, 2030, equal to the lesser of (i) 1% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by the board of directors, provided that not more than 3,724,461 shares of common stock may be issued under the 2020 ESPP. As of December 31, 2022, a total of 95,401 shares had been issued under the 2020 ESPP and 709,682 shares were available for issuance under the 2020 ESPP.

Stock Option Valuation

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model.

Before November 3, 2020, the Company was a private company and until that time lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer public companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its

own traded stock price. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of an option for time periods approximately equal to the expected term of the option. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The expected dividend yield of 0% is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted:

	YEAR ENDED DECEMBER 31,	
	2022	2021
Fair value of common stock	$ 5.72	$ 15.55
Expected term (years)	6.0	6.0
Expected volatility	77.0%	76.4%
Risk-free interest rate	2.22%	0.90%
Expected annual dividend yield	0%	0%

The following table summarizes the Company's stock option activity since December 31, 2021:

	NUMBER OF SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	INTRINSIC VALUE (in thousands)
Outstanding at December 31, 2021	4,339,523	$ 9.75	7.68	$ 8,823
Granted	2,563,920	5.72		
Exercised	(14,757)	1.95		
Forfeited or canceled	(1,530,376)	8.89		
Outstanding at December 31, 2022	5,358,310	$ 8.09	5.26	$ —
Vested and expected to vest at December 31, 2022	5,358,310	$ 8.09	5.26	$ —
Options exercisable at December 31, 2022	2,628,431	$ 8.43	3.81	$ —

The weighted-average grant-date valuation of stock options granted during the years ended December 31, 2022 and 2021 was $3.90 per share and $10.26 per share, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021 was $0.1 million and $3.8 million, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense related to stock options and restricted stock awards was classified in the consolidated statements of operations as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Research and development expenses	$ 3,293	$ 3,243
General and administrative expenses	4,729	5,262
Restructuring charges	381	—
	$ 8,403	$ 8,505

In September 2022, the Company modified the terms of stock options previously granted to one executive officer. As a result of this modification, the Company recorded an expense of approximately $0.2 million within research and development expenses for the year

ended December 31, 2022 to account for the incremental change in the fair value of the stock options before and after the modification.

In connection with a restructuring of the Company, (see Note 13) on November 30, 2022, the Company modified the terms of stock options previously granted to two executive officers and the employees affected by the workforce reduction to extend the period to exercise vested options post-separation. As a result of these modifications, the Company recorded an expense of approximately $0.4 million for the year ended December 31, 2022 to account for the incremental change in the fair value of the stock options before and after the modifications. The total expense of $0.4 million was recognized in restructuring charges.

In September 2021 and November 2021, the Company modified the terms of stock options previously granted to two executive officers. As a result of these modifications, the Company recorded an expense of approximately $1.4 million for the year ended December 31, 2021 to account for the incremental change in the fair value of the stock options before and after the modifications. Of this total expense, $0.9 million was recognized in research and development expenses.

As of December 31, 2022, total unrecognized stock-based compensation expense related to unvested stock-based awards was $12.4 million, which is expected to be recognized over a weighted-average period of 2.5 years.

8. Income Taxes

For the years ended December 31, 2022 and 2021, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period, due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	YEAR ENDED DECEMBER 31,	
	2022	2021
Federal statutory income tax rate	(21.0)%	(21.0)%
State income taxes, net of federal benefit	(4.6)	(6.0)
Federal and state research and development tax credits	(4.1)	(3.8)
Stock-based compensation	2.3	—
Other	0.4	0.6
Change in deferred tax asset valuation allowance	27.0	30.2
Effective income tax rate	0.0%	0.0%

The Company's net deferred tax assets consisted of the following (in thousands):

	DECEMBER 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 50,167	$ 42,897
Research and development tax credit carryforwards	15,253	11,963
Deferred revenue	177	5,036
Accrued expenses	728	782
Operating lease liabilities	7,162	18,892
Stock-based compensation	2,004	2,118
Capitalized research expenses	15,742	—
Other	280	298
Total deferred tax assets	91,513	81,986
Valuation allowance	(84,226)	(62,671)
Total deferred tax assets, net of valuation allowance	7,287	19,315
Deferred tax liabilities:		
Depreciation	(133)	(382)
Operating lease right-of-use assets	(7,154)	(18,933)
Total deferred tax liabilities	(7,287)	(19,315)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had gross U.S. federal net operating loss ("NOL") carryforwards of $185.2 million, which may be available to offset future taxable income, of which $11.3 million begin to expire in 2034 and of which $173.9 million do not expire but are generally limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of

December 31, 2022, the Company had gross state net operating loss carryforwards of $174.1 million, which may be available to offset future taxable income, of which $171.8 million begin to expire in 2035 and $0.7 million may be carried forward indefinitely. As of December 31, 2022, the Company also had U.S. federal and state research and development tax credit carryforwards of $10.4 million and $6.2 million, respectively, which will begin to expire in 2034 and 2030 respectively. The Tax Cuts and Jobs Act (TCJA) requires taxpayers to capitalize and amortize research and experimental (R&D) expenditures under section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during the year and resulted in the capitalization of R&D costs of $66.8 million. The Company is amortizing these costs for tax purposes over 5 years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S.

Utilization of the U.S. federal and state NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and research and development tax credit carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. If a change in control has occurred at any time since the Company's formation, utilization of its pre-change NOLs or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, which could then be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before their utilization. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. Until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 and 2021. Management reevaluates the positive and negative evidence at each reporting period.

The Company generated research credits for the tax years ending after December 31, 2013 but has not conducted a study to document qualified activities. This study may result in an adjustment to the Company's research and development carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an unrecognized tax benefit for the year ended December 31, 2022. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research credit carryforward and the valuation allowance.

For the years ended December 31, 2022 and 2021, the valuation allowance increased primarily due to increases in NOL carryforwards and research and development tax credit carryforwards as well as the increase in stock compensation awards partially offset by a decrease in deferred revenue and was as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Valuation allowance at beginning of year	$ (62,671)	$ (41,894)
Increases recorded to income tax provision	(21,555)	(20,777)
Valuation allowance at end of year	$ (84,226)	$ (62,671)

As of December 31, 2022 and 2021, the Company had not recorded any amounts for unrecognized tax benefits. Interest and penalties related to income taxes are recorded as a component of the income tax provision in the consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the consolidated statements of operations and comprehensive loss.

The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company is open to future tax examination under statute from 2018 to the present; however, carryforward attributes that were generated prior to 2019 may still be adjusted upon examination by federal, state or local tax authorities if they either have been or will be used in a future period. The Company has not received any notice of examination in any jurisdictions for any tax year open under statute.

9. Commitments and Contingencies

Leases

The Company's commitments under its leases are described in Note 10.

License and Supply Agreements

License Agreement with Massachusetts Institute of Technology

In December 2015, the Company entered into an exclusive patent license agreement with the Massachusetts Institute of Technology ("MIT") (the "MIT Agreement"). The MIT Agreement replaced a May 2013 exclusive agreement with MIT. Under the MIT Agreement, the Company received an exclusive license under the licensed patent rights to develop, manufacture and commercialize any products related to certain intracellular delivery methods that were developed at MIT.

Under the MIT Agreement, the Company also has the right to grant sublicenses of its rights during an exclusivity period that commences on the effective date of the MIT Agreement and expires on the date upon which all issued patents under the agreement have expired and all filed patent applications for the defined patent rights have been abandoned. Such sublicenses may extend past the expiration date of the exclusivity period; however, the exclusivity of such sublicenses expires at the end of the exclusivity period. During the exclusivity period, MIT may not grant any other license in the Company's field of use under the licensed patent rights in the MIT Agreement, except that MIT may grant licenses under the agreement to specified parties.

The Company is obligated to use diligent efforts to develop licensed products or licensed processes, to hire a specified number of employees to support the development effort to bring the licensed product or licensed process to commercialization, and to expend a minimum amount in the low single-digit millions annually that must be spent in support of this effort for the term of the MIT Agreement. There are also terms included in the MIT Agreement that require the Company to (i) reach certain thresholds of sublicense income within five years from the date of the amended effective date of the agreement or (ii) expend a minimum amount in the mid single-digit millions within five years on at least one fully funded project towards the development of a licensed product or licensed process. If the Company fails to meet these requirements, MIT may treat such failure as a material breach.

Under the MIT Agreement, the Company is obligated to pay nonrefundable annual license maintenance fees of less than $0.1 million, which may be credited against royalties subsequently due on net sales of licensed products earned in the same calendar year, if any. In addition, the Company is obligated to make aggregate milestone payments to MIT of up to $1.8 million upon the achievement of specified milestones with respect to each licensed product, consisting of up to $0.8 million of development milestone payments and up to $1.0 million of regulatory milestone payments. The Company is also obligated to pay royalties of a low single-digit percentage to MIT based on (i) the Company's, and any of its affiliates' and sublicensees', net sales of licensed products in the research field and (ii) the Company's, and any of its affiliates', net sales of licensed products in the therapeutic field. With respect to licensed products or licensed processes leased or sold by a sublicensee, the Company is required to pay MIT royalties equal to the lesser of a low single-digit percentage of each sublicensees' net sales or a mid double-digit percentage of any royalty owed to the Company under a relevant sublicense agreement. The Company is also required to pay MIT a mid-teens percentage of any other sublicense income that the Company receives from sublicensees. The Company is also responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights.

The license granted by MIT to the Company is an exclusive license for the period from the effective date of the MIT Agreement through the date upon which all issued patents under the agreement have expired and all filed patent applications for the defined patent rights have been abandoned. MIT has the right to terminate the agreement if the Company fails to pay amounts when due or otherwise materially breaches the agreement and fails to cure such nonpayment or breach within specified cure periods or in the event the Company ceases to carry on its business related to the agreement. In the event of a termination due to the Company's breach caused by a failure to meet its diligence requirements for a specified field, but where the Company has fulfilled its obligations with respect to a different specified field, MIT may not terminate the agreement with respect to the different specified field. MIT may immediately terminate the agreement if the Company or any of its affiliates brings specified patent challenges against MIT or assists others in bringing a patent challenge against MIT. The Company has the right to terminate the agreement for its convenience at any time on six months' prior written notice to MIT and payment of all amounts due to MIT through the date of termination.

As of December 31, 2022 and 2021, the Company had no liabilities for amounts owed to MIT under the sublicense terms of the MIT Agreement. During both the years ended December 31, 2022 and 2021, the Company recognized less than $0.1 million in research and development expense under the sublicense terms of the agreement.

License Agreement with Erytech

In June 2019, the Company entered into a license agreement with Erytech Pharma S.A. ("Erytech"), a French biopharmaceutical company developing therapies for severe forms of cancer and orphan diseases. Under the agreement, the Company received an exclusive worldwide license to develop red blood cell-based antigen-specific immune modulating therapies and has the right to grant sublicenses of its rights.

Under the agreement, the Company paid an upfront fee of $1.0 million and is obligated to make aggregate milestone payments of up to $6.0 million upon the achievement of specified milestones, consisting of up to $1.0 million of development milestone payments and

up to $5.0 million of regulatory milestone payments, for the first licensed product to achieve the specified milestones and payments of up to $50.0 million upon the achievement of specified sales milestones for all licensed products successfully developed under this agreement for each indication. In addition, the Company is obligated to pay tiered royalties ranging in the low single-digit percentages of annual net sales for each licensed product or licensed indication sold by the Company or its affiliates. Royalties will be paid by the Company on a licensed product-by-licensed product, indication-by-indication and country-by-country basis beginning on the first commercial sale of such licensed product for such indication in such country until expiration of the last valid patent claim covering such licensed product in such country. With respect to licensed products sublicensed to third parties, the Company is required to pay a low single-digits to low double-digits percentage of any sublicense income that it receives from sublicensees. The Company is also responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights.

The Company has the right to terminate the agreement, in whole or on a country-by-country basis, upon 60 days' notice to Erytech.

In 2019, the Company paid the upfront fee of $1.0 million and recorded this amount as a research and development expense in its consolidated statement of operations and comprehensive loss. As of December 31, 2022 and 2021, the Company had not made any additional payments and had not accrued for any contingent payments as there were no development, regulatory or sales milestones that were probable of being achieved.

Manufacturing Services Agreements

During the years ended December 31, 2021 and 2020, the Company entered into agreements with a contract manufacturing organization to provide manufacturing services related to its product candidates as it began to prepare for future clinical trials. The Company had non-cancelable lease commitments representing one year of lease payments as of December 31, 2022 related to these agreements. These payments are included within the minimum lease payments for fiscal year 2022 in Note 10.

401(k) Plan

The Company sponsors a 401(k) defined contribution benefit plan (the "401(k) Plan"), which covers all employees who meet certain eligibility requirements as defined in the 401(k) Plan and allows participants to defer a portion of their annual compensation on a pre-tax basis. Contributions to the 401(k) Plan may be made at the discretion of management. For the years ended December 31, 2022 and 2021, the Company contributed $0.6 million and $0.4 million, respectively to the 401(k) Plan.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

10. Leases

As of December 31, 2022 and 2021, the Company leased its office and laboratory facilities under a non-cancelable operating lease entered into in December 2018, which includes lease incentives, payment escalations and rent holidays. The Company had not entered into any financing leases or any material short-term operating leases as of December 31, 2022 and 2021.

2018 Lease

In December 2018, the Company entered into a lease for office and laboratory space in Watertown, Massachusetts (the "2018 Lease"). The 2018 Lease term commenced in December 2019 and expires in November 2029. Under the 2018 Lease, the Company has one five-year option to extend the term of the lease. The initial annual base rent was $3.8 million upon entering into the lease, with such base rent increasing during the initial term by 3% annually on the anniversary of the commencement date. The Company is obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, replacement and management of the new leased premises. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $2.3 million, for which the Company is required to maintain a separate cash balance of the same amount.

The 2018 Lease Agreement includes a landlord-provided tenant improvement allowance of $9.8 million that was applied to the costs of the construction of leasehold improvements.

In connection with the Restructuring (see Note 13), the Company completed an evaluation of the impact of the Restructuring on the carrying value of its long-lived assets, including operating lease assets. This process included evaluating the estimated remaining lives, significant changes in the use, and potential impairment charges related to its long-lived assets. Based on its evaluation, the Company determined other long-lived assets, including operating lease assets were not impaired as of December 31, 2022, and it did not recognize any impairment charges related to those long-lived assets for the year ended December 31, 2022. The Company's headquarters facility is actively being marketed for sublease.

Embedded Lease

The Company evaluated its vendor contracts to identify embedded leases, if any, and noted that an agreement entered into in April 2019 with a contract manufacturing supplier constituted a lease under ASC 842 because the Company has the right to substantially all of the economic benefits from the use of the asset and can direct the use of the asset. The embedded lease commenced in September 2019 and initially expired 24 months from the commencement date, with no stated option to extend the term. Upon the commencement date, the Company recorded right-of-use assets and operating lease liabilities in equal amounts of $14.7 million in connection with this embedded lease. At various times in 2020 and 2021, the Company amended the terms of its agreement with the contract manufacturing supplier to allow for an increase in manufacturing runs, and to extend the term of the arrangement resulting in in an increase in the right-of-use asset and lease liability. On November 1, 2022, as part of a transition to a more cost-effective manufacturing format, the Company provided notice to terminate the relevant statements of work under its agreement with the contract manufacturing supplier. The agreement required a nine-month prior written notice of termination, which results in an estimated termination date of July 31, 2023. As a result of the termination, the Company reduced its remaining lease payments by approximately $36.7 million. The termination was accounted for as a lease modification in the three months ending December 31, 2022 and reduced the right of use asset and lease liability by approximately $32.3 million.

Lease agreement

The Company's 2018 lease agreement has a term of ten years. As noted above, the 2018 Lease includes an option to extend the lease for up to five years. This option would only be included in the determination of the amount of the lease liability when it is reasonably certain that the option will be exercised. When determining if a renewal option is reasonably certain of being exercised, the Company considers several economic factors, including, but not limited to, the significance of leasehold improvements incurred on the property, whether the asset is difficult to replace, underlying contractual obligations or specifics unique to that particular lease that would make it reasonably certain that the Company would exercise such option. Renewal and termination options were not included in the lease term for the Company's new and existing operating leases as these options were not reasonably certain of being exercised.

Right-of-use assets under operating leases at December 31, 2022 and 2021 totaled $27.4 million and $69.8 million, respectively. The leases do not include any restrictions or covenants that had to be accounted for under the lease guidance.

Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at December 31, 2022 were as follows (in thousands):

YEAR ENDING DECEMBER 31,		
2023	$	8,663
2024		4,297
2025		4,426
2026		4,559
2027		4,696
Thereafter		9,393
Total lease payments		36,034
Less: Imputed interest		(8,563)
Total operating lease liabilities	$	27,471

Lease Portfolio

The components of lease cost and supplemental information for the Company's lease portfolio were as follows (in thousands, except term and discount rate amounts):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Lease cost:		
Operating lease cost	$ 14,295	$ 13,725
Variable lease cost	1,878	1,963
	$ 16,173	$ 15,688

	DECEMBER 31,	
	2022	2021
Weighted-average remaining lease term (in years)	6.1	6.2
Weighted-average discount rate%	8.8%	7.6%

Supplemental cash flow information related to the Company's operating leases was as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Cash paid for amounts included in the measurement of operating lease liabilities:		
Operating cash flows from operating leases	$ 14,591	$ 12,611

11. License and Collaboration Agreements

2017 License and Collaboration Agreement with Roche

In April 2017, the Company entered into a second license and collaboration agreement with Roche (the "2017 Roche Agreement") to allow Roche to use the Company's Cell Squeeze technology to enable gene editing of immune cells to discover new targets in cancer immunotherapy. The 2017 Roche Agreement included several licenses granted by Roche to the Company and by the Company to Roche in order to conduct a specified research program in accordance with a specified research plan.

In early 2022, the Company received notice that the 2017 Roche Agreement was terminated and all active work streams under the 2017 Roche Agreement were concluded, and as of December 31, 2021, the Company concluded that it expected to incur no additional costs to satisfy the remaining performance obligations under the 2017 Roche Agreement and the Company recognized revenue of $1.2 million under the 2017 Roche Agreement. There was no remaining deferred revenue under the 2017 Roche Agreement as of December 31, 2021.

2018 License and Collaboration Agreement with Roche

In October 2018, the Company entered into a third license and collaboration agreement with Roche (the "2018 Roche Agreement") to jointly develop certain products based on mononuclear antigen presenting cells ("APCs"), including human papilloma virus ("HPV"), using the SQZ APC platform for the treatment of oncology indications. The Company granted Roche a non-exclusive license to its intellectual property, and Roche granted the Company a non-exclusive license to its and its affiliates' intellectual property for the purpose of performing research activities. In connection with this agreement, the parties terminated the 2015 Roche Agreement described above. The 2018 Roche Agreement has a term that extends until all royalty, profit-share and other payment obligations expire or have been satisfied. Roche has the right to terminate the 2018 Roche Agreement, in whole or on a product-by-product basis, upon a specified amount of notice to the Company. The Company or Roche may terminate the agreement if the other party fails to cure its material breach within a specified period after receiving notice of such breach.

Under the 2018 Roche Agreement, Roche was granted option rights to obtain an exclusive license to develop APC products or products derived from the collaboration programs on a product-by-product basis. These option rights are exercisable upon the achievement of clinical Phase 1 proof of concept and expire, if unexercised, as of a date specified in the agreement. In addition, Roche was granted an option right to obtain an exclusive license to develop a Tumor Cell Lysate ("TCL") product. This option right is exercisable upon the achievement of clinical proof of concept and expires, if unexercised, as of a date specified in the agreement. For each of the APC products and TCL product, once Roche exercises its option and pays a specified incremental amount ranging from

$15.0 million to $50.0 million for APC products and of $100.0 million for the TCL product, Roche will receive worldwide, exclusive commercialization rights for the licensed products, subject to the Company's alternating option to retain U.S. APC commercialization rights. The Company will retain worldwide commercialization rights to any APC products or the TCL product for which Roche elects not to exercise its applicable option. For the first APC product that Roche exercises its option, Roche will receive worldwide, exclusive commercialization rights for the licensed product. On a product-by-product basis for the APC products, after the first product option is exercised by Roche and for every other product for which Roche exercises its option, the Company will retain an option to obtain the exclusive commercialization rights in the United States. Upon exercise of the TCL option by Roche, (i) the Company will be entitled to receive the aforementioned milestone payment of $100.0 million and (ii) profits from the TCL product will be shared equally by the Company and Roche. Through December 31, 2022 and 2021 Roche had not exercised any of its options under the 2018 Roche Agreement.

Under the 2018 Roche Agreement, the Company received an upfront payment of $45.0 million and is eligible to receive (i) reimbursement of a mid double-digit percentage of its development costs; (ii) aggregate milestone payments on a product-by-product basis of up to $1.6 billion upon the achievement of specified milestones, consisting of up to $217.0 million of development milestone payments, up to $240.0 million of regulatory milestone payments and up to $1.2 billion of sales milestone payments; and (iii) tiered royalties on annual net sales of APC and TCL products licensed under the agreement, as described below. The Company received the upfront payment of $45.0 million in October 2018 upon execution of the agreement. In addition, during the second quarter of 2019, the Company received a payment of $10.0 million following the achievement of the first development milestone under the 2018 Roche Agreement related to submission by the Company of preclinical data to the U.S. Food and Drug Administration ("FDA"), and during the first quarter of 2020, the Company received a payment of $20.0 million following the achievement of the second development milestone under the 2018 Roche Agreement related to first-patient dosing in a Phase 1 clinical trial.

Roche will pay tiered royalties based on annual net sales of APC and TCL products. If Roche exercises its option to obtain a license to commercialize an APC product, Roche will pay the Company tiered royalties on annual net sales of that licensed product at rates ranging from a mid single-digit percentage to a mid-teens percentage, depending on net sales of the product. If the Company exercises its option to obtain a license to develop an APC product in the United States, it will pay Roche tiered royalties on annual net sales of that licensed product at rates ranging from a mid single-digit percentage to a mid-teens percentage, depending on net sales of the product in the United States. For APC products selected by Roche, rather than mutually, Roche will pay the Company royalties on annual net sales of that licensed product at rates ranging from a mid single-digit percentage to a high single-digit percentage, depending on net sales of the product. For APC products that are selected mutually and for which the Company has not exercised its option to commercialize the product in the United States, Roche will pay the Company tiered royalties on annual net sales of that licensed product at a rate ranging from a high single-digit percentage to a mid-teens percentage, depending on net sales of the product. For TCL products, Roche will pay the Company tiered royalties on the aggregate net sales of all TCL products at rates ranging from either a mid-single digit percentage to a percentage in the low twenties, with the caveat that the rates for sales in the United States may instead range from a low-teens percentage to a percentage in the mid twenties, depending on whether and when the Company opts out of sharing certain profits and costs of commercializing the TCL product in the United States with Roche.

The Company assessed its accounting for the 2018 Roche Agreement in accordance with ASC 606 and concluded that Roche is a customer prior to the exercise of any of its options under the agreement. The Company also identified the following promises under the 2018 Roche Agreement: (i) a non-exclusive license granted to Roche to use the Company's intellectual property and collaboration compounds to conduct research activities related to the research plans under the 2018 Roche Agreement; (ii) specified research and development services related to HPV through Phase 1 clinical trials under a specified research plan; (iii) manufacturing of the Company's SQZ APC platform and equipment in order to support the HPV research plan; (iv) specified research and development services on next-generation APCs under a research plan; (v) specified research and development services on TCL under a research plan; and (vi) participation on a joint steering committee ("JSC").

The Company concluded that, in the case of each performance obligation, the license to its intellectual property was not distinct as a result of Roche being unable to benefit from the license on its own or with other resources reasonably available in the marketplace because the license to its intellectual property requires significant specialized capabilities in order to be further developed. The Company concluded that the license to its intellectual property, research and development activities related to HPV, and manufacturing of the Company's SQZ APC platform and equipment related to HPV were not distinct from each other because the research and manufacturing activities together customize and significantly modify the underlying technology. As such, the Company determined that each of these related promises under the agreement was not distinct from the others in this group and should be combined into a single performance obligation. The Company also concluded that the license to its intellectual property and the research and development activities on next-generation APCs were not distinct from each other because the research and development activities customize and significantly modify the underlying technology. As such, the Company determined that these related promises should be combined into a single performance obligation. Further, the Company concluded that the license to its intellectual property and the research and development activities on TCL were not distinct from each other because the research and development activities customize and significantly modify the underlying technology. As such, the Company determined that these related promises should be combined into a single performance obligation. The Company concluded that the three performance obligations were distinct from each other as they are separate programs and are unrelated. In addition, the Company determined that the impact of participation on the JSC was insignificant and had an immaterial impact on the accounting model.

Finally, the Company evaluated the option rights for licenses to develop, manufacture and commercialize the collaboration targets to determine whether these options provide Roche with any material rights for accounting purposes. The Company concluded that the option exercise prices were not below respective standalone selling prices, and, therefore, the options were marketing offers that do not provide material rights under ASC 606. Accordingly, the options were excluded as performance obligations at the outset of the 2018 Roche Agreement and will be accounted for as separate accounting contracts if and when each option exercise occurs.

Based on these assessments, the Company identified three performance obligations at the outset of the 2018 Roche Agreement: (1) the license to the Company's intellectual property, the research and development activities related to HPV through Phase 1 clinical trials under a specified research plan, and the manufacturing of the Company's SQZ APC platform and equipment in order to support the HPV research plan (the "first performance obligation"); (2) the license to the Company's intellectual property and the research and development activities on next-generation APCs (the "second performance obligation"); and (3) the license to the Company's intellectual property and the research and development activities on TCL (the "third performance obligation").

During the fourth quarter of 2019, the Company evaluated its overall program priorities and determined that in 2020 it would continue to focus its resources on progressing the specified APC programs related to the 2018 Roche Agreement as well as its Activating Antigen Carriers ("AAC") and Tolerizing Antigen Carriers ("TAC") platforms. As a result of its continuing focus on these specific programs, the Company reduced the level of priority of the TCL research activities under the 2018 Roche Agreement and expects to perform such TCL research activities over a longer time period than as originally expected under the specified research plan of the agreement. Since the fourth quarter of 2019, the Company had classified $9.2 million as non-current deferred revenue in its consolidated balance sheet which will remain unrecognized as revenue until TCL research activities resume or the 2018 Roche Agreement is modified by the Company and Roche. In the fourth quarter of 2022, the Company determined that based on its internal plans which did not include work on TCL since 2019, and which do not anticipate performing work on TCL in the future prior to the expiration of the option right, as well as Roche's concurrence that no work was performed or expected to be performed in 2023, that it could recognize the remaining deferred revenue of $9.2 million. Accordingly, as of December 31, 2022, there was no deferred revenue associated with the TCL performance obligation.

The Company separately recognizes revenue associated with its performance obligations as the research, development and manufacturing services are provided using an input method, based on the cumulative costs incurred compared to the total estimated costs expected to be incurred to satisfy each performance obligation. The transfer of control to the customer occurs over the time period that the research and development services are to be provided by the Company, and this cost-to-cost method is, in management's judgment, the best measure of progress towards satisfying each performance obligation. The amounts received that have not yet been recognized as revenue are deferred as a contract liability in the Company's consolidated balance sheet and will be recognized over the remaining research and development period until each performance obligation is satisfied.

During the year ended December 31, 2022, there were no changes in the total estimated costs expected to be incurred to satisfy the performance obligations under the 2018 Roche Agreement. During the year ended December 31, 2021, the total estimated costs expected to be incurred to satisfy the performance obligations decreased by $7.3 million. In the fourth quarter of 2021, the Company became entitled to receive a milestone payment of $3.0 million upon (i) the recommendation by an independent panel that we could advance our SQZ-PBMC-HPV clinical trial to combination therapy to checkpoint initiators and (ii) the initiation of that therapy. The Company achieved both requirements in the fourth quarter of 2021 and therefore included the $3.0 million milestone payment in its estimate of the transaction price for the 2018 Roche Agreement. As a result, the Company recorded a cumulative catch-up adjustment to collaboration revenue of $2.5 million during the year ended December 31, 2021.

The Company recognized revenue of $21.0 million and $25.8 million during the years ended December 31, 2022 and 2021, respectively, under the 2018 Roche Agreement. Of the $21.0 million of revenue recognized during the year ended December 31, 2022, $9.2 million was related to the third performance obligation (TCL) and $11.8 million was related to the first performance obligation. As of December 31, 2022 and 2021, the Company recorded as a contract liability deferred revenue related to the 2018 Roche Agreement of $0.2 million and $21.2 million, respectively, of which $0.2 million and $12.0 million, respectively, were current liabilities. As of December 31, 2022, the research and development services related to the remaining performance obligation was expected to be performed over remaining period of three to six months.

Contract Liability

The changes in the total contract liability (deferred revenue) balances related to the Company's license and collaboration agreements with Roche were as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Balance at beginning of period	$ 21,203	$ 45,201
Deferral of revenue	—	3,100
Recognition of deferred revenue	(21,029)	(27,098)
Balance at end of period	$ 174	$ 21,203

During the years ended December 31, 2022 and 2021, the Company recognized revenue of $21.0 million and $24.5 million, respectively, related to deferred revenue that was recorded as a contract liability at the beginning of each respective year.

12. Net Loss per Share

Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	YEAR ENDED DECEMBER 31,	
	2022	2021
Numerator:		
Net loss	$ (79,464)	$ (68,741)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	28,812,904	27,578,844
Net loss per share, basic and diluted	$ (2.76)	$ (2.49)

The Company's potential dilutive securities, which consist of common stock options have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	YEAR ENDED DECEMBER 31,	
	2022	2021
Stock options to purchase common stock	5,358,310	4,339,523
	5,358,310	4,339,523

13. Restructuring

On November 30, 2022, the Company's Board of Directors approved a restructuring plan and strategic prioritization (the "Restructuring") of its clinical portfolio to concentrate on the development of its second-generation enhanced Antigen Presenting cells (eAPC) cell therapy program. In connection with the Restructuring, the Company paused clinical programs, terminated operations in its Hong Kong and China subsidiaries and the Board of Directors approved a workforce reduction of approximately 60%, including research and development and general and administrative support functions in the United States and China. In connection with the prioritization decision, the Company's Chief Executive Officer stepped down from his roles as CEO and member of the Board of Directors.

The following table summarizes the activity for accrued restructuring costs for the year ended December 31, 2022 (in thousands):

	Employee Related Costs	Facility Related Costs	Total
Balance as of December 31, 2021	$ —	$ —	$ —
Expenses incurred	4,459	400	4,859
Payments	(895)	—	(895)
Non-cash charges	(402)	(400)	(802)
Balance as of December 31, 2022	$ 3,162	$ —	$ 3,162

During the year ended December 31, 2022, the Company recorded $4.9 million of restructuring charges. Employee-related costs of $4.5 million primarily relate to salary continuance and one-time termination benefits to the affected employees, including severance and healthcare benefits, including non-cash charges of $0.4 million from the modification of stock options. Facility related costs of $0.4 million relate to accelerated depreciation on laboratory equipment that is no longer required and will be disposed of.

In addition to accelerating the depreciation expense of certain laboratory equipment, the Company also completed an evaluation of the impact of the Restructuring on the carrying value of its other long-lived assets, such as operating lease assets. This process includes evaluating the estimated remaining lives, significant changes in the use, and potential impairment charges related to its long-lived assets. Based on its evaluation, the Company determined other long-lived assets were not impaired as of December 31, 2022, and it did not recognize any impairment charges related to those long-lived assets for the year ended December 31, 2022. The Company’s headquarters facility is actively being marketed for sublease.

The accrued restructuring liability of $3.2 million is payable within the next twelve months and has been included as accrued restructuring costs in current liabilities in the consolidated balance sheet. The remaining accrued restructuring charges are subject to assumptions, and actual amounts may differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Restructuring.

14. Subsequent Events

On March 10, 2023, SVB, one of the Company's financial institutions, was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. At the time of closing, the Company had substantially all of its cash and cash equivalents at SVB or managed by SVB at a separate institution, and all of its restricted cash of $2.3 million supporting one outstanding letter of credit at SVB. Based upon the announcement on March 12, 2023, from the U.S. Department of the Treasury, the U.S. Federal Reserve and the FDIC, the Company expects to have access to all of its deposits at SVB and the separate institution.

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