

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, 2023

OR

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

For the quarterly period from _____ to _____

Commission File Number 001-40440

Senti Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

86-2437900
(I.R.S. Employer
Identification Number)

2 Corporate Drive, First Floor
South San Francisco, CA 94080
(Address of principal executive offices and zip code)

(650) 239-2030
(Registrant's telephone number, including area code)

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, par value \$0.0001 per share	SNTI	The Nasdaq Capital Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 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 (Section 232.405 of this chapter) during the preceding 12 months (or 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
Non-accelerated filer

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

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the registrant was approximately \$23.5 million (based on the closing price of the registrant's common stock as reported on The Nasdaq Global Select Market on that date).

As of March 18, 2024 there were 45,755,021 shares of the registrant's common stock, par value \$0.0001 per share, were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to its 2024 Annual Meeting of Stockholders (the "Proxy Statement"), which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission (the "SEC") not later than 120 days after the registrant's fiscal year end of December 31, 2023 or an amendment on Form 10-K/A filed with the SEC within 120 days after the end of the registrant's fiscal year, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

SENTI BIOSCIENCES, INC.
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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (“Annual Report” or “Form 10-K”) and some of the information incorporated by reference, includes forward-looking statements regarding, among other things, the plans, strategies, and prospects, both business and financial, of Senti Biosciences, Inc. (“Senti” or the “Company”). These statements are based on the beliefs and assumptions of the management of Senti. Although Senti believes that their respective plans, intentions, and expectations reflected in or suggested by these forward-looking statements are reasonable, it cannot assure you that it will achieve or realize these plans, intentions, or expectations. Forward-looking statements are inherently subject to risks, uncertainties, and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or results of operations, and any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These statements may be preceded by, followed by or include the words “believes”, “estimates”, “expects”, “projects”, “forecasts”, “may”, “might”, “will”, “should”, “seeks”, “plans”, “scheduled”, “possible”, “anticipates”, “intends”, “aims”, “works”, “focuses”, “aspires”, “strives” or “sets out” or similar expressions. Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements which speak only as of the date hereof. Forward-looking statements contained in this Annual Report include, for example, statements about:

- the accuracy of our estimates and projections of financial information, including expenses, capital requirements, cash utilization and runway, need for additional financing and market opportunities;
- our ability to maintain the listing of our common stock on Nasdaq, and the potential liquidity and trading of such securities;
- our ability to execute and realize potential benefits from our strategic plans, including our plan to focus internal resources on SENTI-202, to develop a product candidate for the SENTI-301A program through our partnership with Celest Therapeutics (Shanghai) Co. Ltd (“Celest Therapeutics”) in China, and to develop gene circuits for other programs, as announced in January 2024;
- our ability to obtain adequate funding for our ongoing and planned operations;
- the initiation, cost, timing, progress and results of research and development activities, preclinical studies and clinical trials with respect to our current and potential future product candidates;
- our ability to develop and advance our gene circuit platform technologies;
- our ability to identify future product candidates using our gene circuit platform technologies;
- our ability to develop and commercialize product candidates;
- our ability to file and obtain clearance for any additional investigational new drug application, or IND, for any other product candidates we may identify, and to initiate and successfully complete our planned Phase I clinical trial for SENTI-202 and any other product candidates;
- our ability to progress collaboration with Celest Therapeutics in China for a product candidate for the SENTI-301A program;
- our ability to advance our current and potential future product candidates into, and successfully complete, preclinical studies and clinical trials;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- our ability to obtain and maintain regulatory approval of our current and potential future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;

- our ability to obtain and maintain intellectual property protection for our technologies and any of our product candidates;
- the rate and degree of market acceptance of our current and any potential future product candidates, if approved;
- regulatory developments and approval pathways in the United States and international jurisdictions;
- our ability to attract and retain strategic collaborators with development, regulatory, and commercialization expertise;
- the potential benefits of strategic collaboration agreements and our ability, and the ability of our collaborators, to successfully develop technologies and product candidates under the respective collaborations;
- potential liability from lawsuits and penalties related to our technologies, product candidates and current and future relationships with third parties, including relationships under strategic and financing transactions;
- our success in retaining or recruiting, or adapting to changes in, our officers, key employees, or directors;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately under those arrangements;
- our ability to compete effectively with rapidly evolving cell therapy technologies and respond to other developments relating to our existing competitors and new market entrants;
- potential effects of extensive government regulation;
- our future financial performance and capital requirements;
- our ability to implement and maintain effective internal controls;
- the impact of supply chain disruptions;
- expectations regarding our growth, strategy, progress and timing of our clinical trials, including the anticipated dosing of patients and availability of data, and the timing thereof;
- the extent, timing and financial aspects of the reduction in workforce and our strategic prioritization plans;
- unfavorable global economic conditions, including inflationary pressures, market volatility, acts of war and civil and political unrest; and
- other factors detailed under the section entitled “Risk Factors.”

These and other factors that could cause actual results to differ from those implied by the forward-looking statements in this Annual Report described under the heading “Risk Factors” and elsewhere in this Annual Report. The risks described under the heading “Risk Factors” are not exhaustive. New risk factors emerge from time to time and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on the business of Senti or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements attributable to Senti or to persons acting on our behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligations to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

PART I

Item 1. Business

Unless the context otherwise requires, for purposes of this section, the terms “we,” “us,” “our,” “our Company,” “the Company” or “Senti” refer to Senti Biosciences, Inc. and its subsidiaries.




Overview

We are a clinical-stage biotechnology company developing next-generation cell and gene therapies engineered with our gene circuit platform technologies for patients living with incurable diseases. Our mission is to create a new generation of smarter medicines that outsmart complex diseases using novel and unprecedented approaches. To accomplish this mission, we have built a synthetic biology platform that we believe may enable us to program next-generation cell and gene therapies with gene circuits. These gene circuits, which we created from novel and proprietary combinations of DNA sequences, are designed to reprogram cells with biological logic to sense inputs, compute decisions and respond to their respective cellular environments. Using gene circuits, our product candidates are designed to precisely kill cancer cells, spare healthy cells, increase specificity to target cells and control the expression of drugs even after administration. We are applying our gene circuit technologies to develop a pipeline of medicines that use off-the-shelf chimeric antigen receptor natural killer (“CAR-NK”) cells with the goal of addressing major challenges and providing potentially lifesaving treatments for people living with cancer.

Our lead product candidates utilize off-the-shelf healthy adult donor derived NK cells to create CAR-NK cells outfitted with Gene Circuit technologies in several oncology indications with high unmet need. We expect to initiate clinical trials of two of our product candidates in 2024. Our lead product candidate SENTI-202, a potentially first-in-class Logic Gated off-the-shelf CAR-NK cell therapy for the treatment of acute myeloid leukemia (“AML”), received clearance of its Investigational New Drug application (“IND”) by the U.S. Food and Drug Administration (“FDA”) in December 2023, and we anticipate dosing the first patient with SENTI-202 in the second quarter of 2024. Our second clinical development program SENTI-301A, a multi-armed off-the-shelf healthy donor derived CAR-NK cell therapy, is expected to begin in the second quarter of 2024.

Our Pipeline

We are primarily focused on off-the-shelf CAR-NK cell therapy programs for oncology indications. Our lead product candidate, SENTI-202, is on track to begin dosing patients in a Phase 1 clinical trial for the treatment of hematological malignancies including AML in the second quarter of 2024. We also have three partnered programs: (i) our SENTI-301A pipeline program for the treatment of HCC is partnered in China with Celest Therapeutics, (ii) our partnered programs related to gene therapies for tissue-directed targets with Spark Therapeutics, Inc. (“Spark Therapeutics”) and (iii) our partnered programs related to cell therapies for regenerative medicines with BlueRock Therapeutics, Inc. (“BlueRock Therapeutics”). Our most advanced programs, SENTI-202 and SENTI-301A, originate from our internal pipeline of off-the-shelf CAR-NK programs.

Program	Target/Disease Candidate	Preclinical	Early Stage Clinical	Late Stage Clinical	Collaborator
SENTI-202	AML, MDS and other blood cancers	Initial clinical data by YE 2024			
SENTI-301A	HCC and other solid tumors	First patient dosing in 2Q 2024			
Multiple Gene Therapy Programs	Eye, CNS and liver diseases				
Multiple iPSC Cell Therapy Programs	Regenerative medicine				

Our Strategy

Our goal is to maintain and build upon our leadership position in the cell and gene therapy landscape utilizing our proprietary gene circuit technology and synthetic biology expertise. We are pursuing this goal by leveraging our unique approach to programming gene circuits, which we believe may be broadly applicable toward engineering optimal efficacy, precision and control into cell or gene-based medicines, rapidly advancing our pipeline of off-the-shelf CAR-NK cell therapies for oncology indications and establishing strategic collaborations/partnerships to support our non-oncology programs and manufacturing.

We plan to develop and, if approved, commercialize allogeneic cell therapy products for the treatment of cancer. We believe achieving this goal will play a critical role in addressing major challenges in oncology and providing potentially lifesaving treatments for people living with cancer.

Key elements of our strategy include:

- Advance internal pipeline of off-the-shelf CAR-NK cell therapies for oncology indications through the clinical development of our lead product candidate, SENTI-202;
- Advance the clinical development of the SENTI-301A program work through a strategic partnership with Celest Therapeutics;
- Leverage partnering to support non-oncology indications, including our ongoing partnerships with Spark Therapeutics to develop gene therapies for tissue-directed targets, and with BlueRock Therapeutics to develop cell therapies for regenerative medicines;
- Establish additional value-creating collaborations to access the full potential of our technology in additional modalities including T cells, tumor infiltrating lymphocytes (TILs), stem cells including induced

Pluripotent Stem Cells (iPSCs) and Hematopoietic Stem Cells (HSCs), *in vivo* gene therapy such as adeno associated virus (AAV), and messenger ribonucleic acid (mRNA).

SENTI-202 for the Potential Treatment of Hematologic Malignancies including Acute Myeloid Leukemia

Overview

Our lead product candidate SENTI-202 is a potentially first-in-class Logic Gated off-the-shelf CAR-NK cell therapy designed to selectively target and eliminate CD33 and/or FLT3 expressing hematologic malignancies, including AML, while sparing healthy bone marrow cells. We are on track to begin clinical trials in the United States and Australia in 2024 with the first patient anticipated to be dosed in the second quarter of 2024.

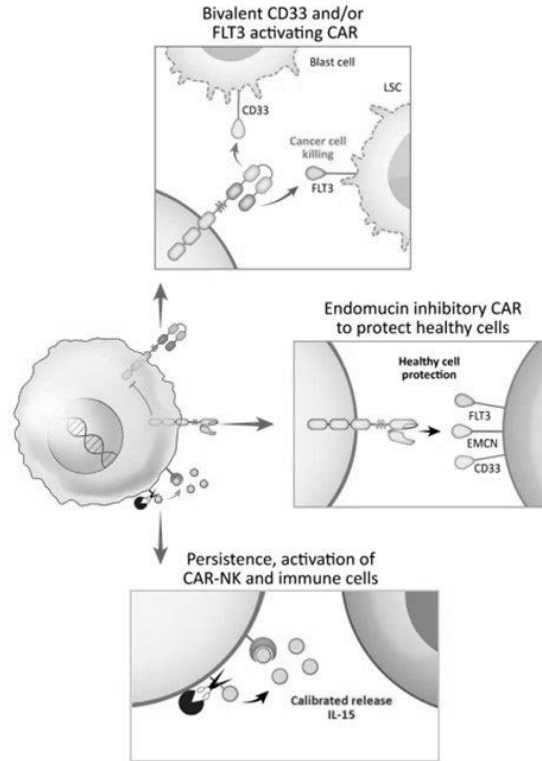
SENTI-202 has been designed to incorporate three chimeric proteins using a Logic Gated gene circuit and delivered through a single retrovirus.

The first chimeric protein that we have engineered SENTI-202 to express is a bivalent CAR as an OR GATE directed against the tumor-associated antigens (“TAAs”), CD33 and/or FLT3, where one or both are expressed in 95% of AML patients. CD33 is typically found on bulk AML blasts and FLT3 is typically found on leukemic stem cells (“LSCs”). LSCs are a rare sub-population of AML cells that possess stem cell like properties of self-renewal and drug resistance, contributing to relapse and poor prognosis after treatment. We believe that targeting FLT3 in addition to CD33 could result in deeper and more prolonged remissions.

In order to protect the healthy cells that express FLT3, the second chimeric protein we have engineered SENTI-202 to include is an inhibitory CAR (“iCAR”), which we refer to as a NOT Gate, to protect the healthy cells from potential on-target/off-tumor toxicity. The iCAR is designed to recognize the healthy cell surface protein endomucin (EMCN). EMCN was chosen as the protective antigen using a multi-step unbiased bioinformatics pipeline designed to identify a cell surface antigen specifically expressed on healthy HSCs but absent on AML tumor cells including both blasts and LSCs. EMCN is expressed on healthy cells, specifically HSCs (and early progenitors) which we believe will confer protection from an activating CAR (“aCAR”)-mediated cytotoxicity on EMCN-expressing cells, even if those cells express CD33 and/or FLT3, thus expected to impart selectivity to SENTI-202 anti-cancer cytotoxicity.

The final protein in the SENTI-202 Gene Circuit is a calibrated release interleukin-15 (“crIL15”), an engineered protein technology that is designed with a protease cleavage site to be able to express and release cytokines from the cell in a calibrated fashion via a protease ubiquitously expressed by the cell. We believe that crIL15 stimulates surrounding immune cells and promotes CAR-NK cell expansion, persistence, and tumor killing activity. The SENTI-202 gene circuit design was systematically optimized through evaluation of over 500 constructs by initially optimizing each component separately and then together.

The following figure illustrates the design of SENTI-202 Logic Gating gene circuits to kill AML LSCs and blasts, while sparing healthy HSCs via (CD33 OR FLT3) NOT EMCN logic.



Acute Myeloid Leukemia (AML): an Unmet Medical Need

Almost 10% of new cancer cases in the United States each year are hematologic malignancies, including leukemia, lymphoma and myeloma. AML is a type of acute leukemia characterized by an accumulation of malignant immature white blood cells. It is the most common type of acute leukemia in adults, constituting 80% to 85% of cases, and is the second most common—as well as the deadliest—in children. Due to the absence of highly efficacious therapies, AML has poor prognosis with a low five-year survival rate at just 30.5%.

Patients with CD33 and/or FLT3 expressing malignancies, which includes myeloid malignancies such as AML, have a grim prognosis and a high unmet need. AML is typically a disease of the elderly with a median age of diagnosis being approximately 65 years. The treatment at diagnosis for the majority of patients who cannot tolerate the toxicities of intensive chemotherapy includes either hypomethylating agents or low-dose cytosine arabinoside (“Ara-C”, also known as cytarabine), as monotherapy or in combination with venetoclax, or best supportive care. In patients who can tolerate more intensive treatments, the goal of treatment is to induce a complete remission (“CR”) with intensive chemotherapy and consolidate with allogeneic hematopoietic cell transplantation (“HCT”). Treatment is combined with the respective targeted agents in patients who have CD33-positive disease or a FLT3-mutated disease (Mylotarg USPI; Rydapt USPI; Xospata USPI). Other therapies for AML include targeted agents for the minority of patients with either isocitrate dehydrogenase (IDH)-1 or IDH-2 mutated disease. Despite these therapies being recently approved for patients with AML, the prognosis continues to be poor with the majority of patients refractory to or relapsing from front-line therapy and a median overall survival (OS) of 5 months at relapse.

Development of targeted AML treatments is difficult because the disease is highly heterogeneous. More than 200 types of chromosome translocations and mutations have been identified in AML patients. Therapies targeting a single TAA are therefore often insufficient to kill all the cancer cell subsets in AML, leading to eventual disease relapse. To drive patients into deeper remissions and prevent relapses, therapies designed to target multiple AML antigens are needed. Additionally, recent studies suggest relapse is associated with the less targeted AML subpopulation of LSCs. Thus, the development of therapies targeting AML LSCs is sorely needed, but this has been

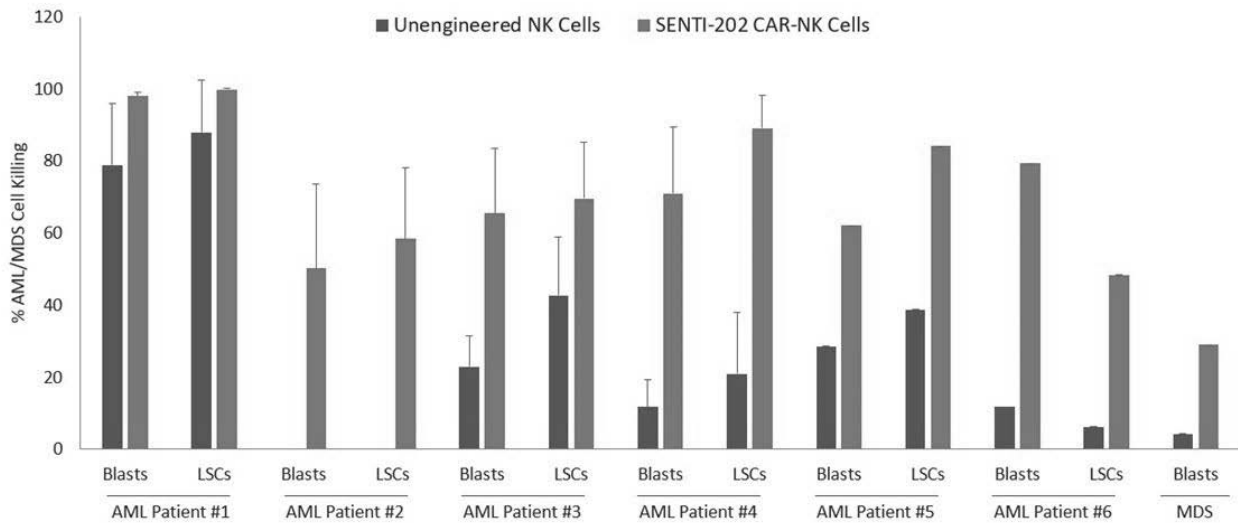
challenging because LSC targets are often expressed on healthy cells, such as HSCs, leading to on-target, off-tumor treatment-induced toxicities.

CAR Cell Therapy for AML

The therapeutic administration of CAR cell therapies has considerably advanced the treatment of certain cancers, such as B-cell malignancies. However, the successes of CAR cell therapies have not yet translated to successful treatment of AML, in part due to the absence of AML-specific target antigens. Due to their nonrestrictive expression, most AML antigens are also expressed on healthy HSCs or myeloid cells. Thus, on-target, off-tumor killing effects of the therapy may lead to the ablation of hematopoietic stem, progenitor or myeloid cells. This off-tumor killing of HSCs leads to serious clinical sequelae including sepsis and febrile neutropenia contributing to morbidity and mortality. Thus, the identification of antigens that enable more robust targeting of AML cells, including LSCs, along with new strategies to reduce off-target killing of HSCs, are critically needed to realize the promise of CAR cell therapies for AML treatment. These described challenges also extend to other potential AML therapeutic modalities, such as antibodies and bispecific T cell engagers.

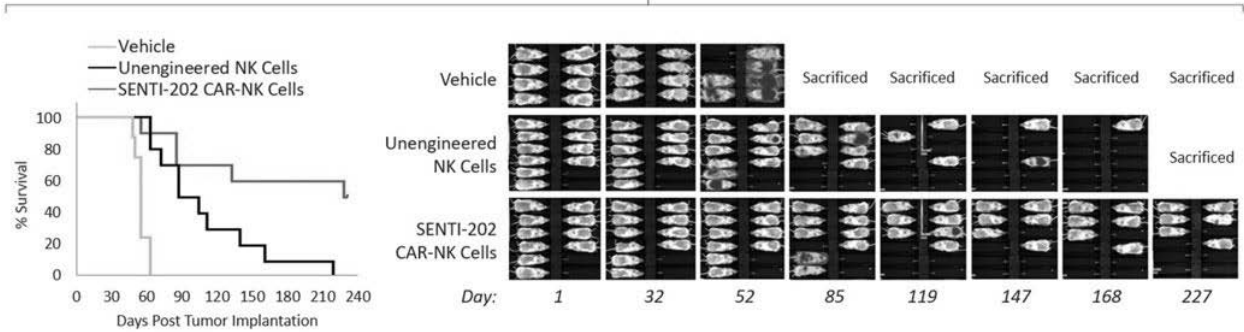
SENTI-202 Preclinical Data

In preclinical studies, as shown below, in comparison to non-engineered NK cells, SENTI-202 CAR-NK cells exhibited increased and more consistent cell killing across a variety of primary patient AML or MDS blasts, or AML leukemia stem cells *in vitro*.

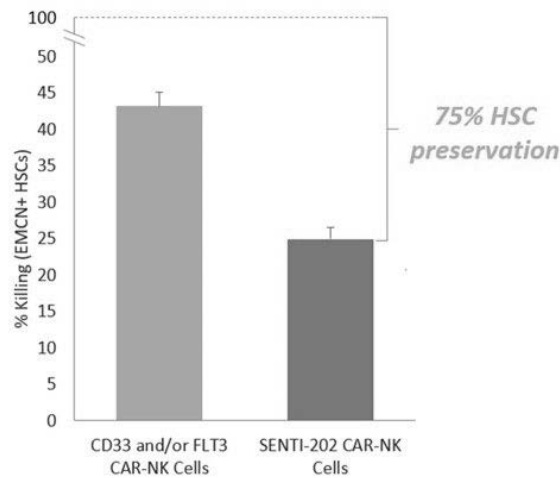


Similarly, in a luciferase tagged MV4-11 AML xenogenic tumor model in immunocompromised mice, decreased bioluminescence indicating decrease in AML tumor burden, and increased survival were observed when the mice were treated with a single dose of SENTI-202 compared to non-engineered NK cells or vehicle control.

	Median Survival (days)
Vehicle	56
Unengineered NK Cells	97
SENTI-202 CAR-NK Cells	230



AML cell line or healthy primary HSCs were co-cultured with either a CAR-NK cell that only expressed the aCAR (i.e. CD33 and/or FLT3 CAR) or SENTI-202 (i.e., with the aCAR and the EMCN-recognizing iCAR). Preclinical data also demonstrated identical killing activity of the leukemia cells with both CAR-NKs and significant selective protection of healthy HSC when exposed to SENTI-202 demonstrating *in vitro* protection of healthy cells from our proprietary EMCN targeting NOT gate.



In preclinical studies, 1:1:1 ratio of effector cells were injected with model leukemia cells that expressed CD33 and FLT3 target antigens, and model “healthy” cells that expressed CD33, FLT3 and the protective EMCN antigen. The three effector cells used in this experiment were either non-engineered NK cells, CAR-NK cells with just the CD33 and/or FLT3 aCAR, and SENTI-202. Results demonstrated that in the SENTI-202 group, leukemia cells were selectively killed while the model “healthy” cells were spared after greater than 3 weeks *in vivo*. In the other two groups, there was non-selective killing of both the leukemia and the “healthy” cells.

Development Plan and Key Next Steps for SENTI-202

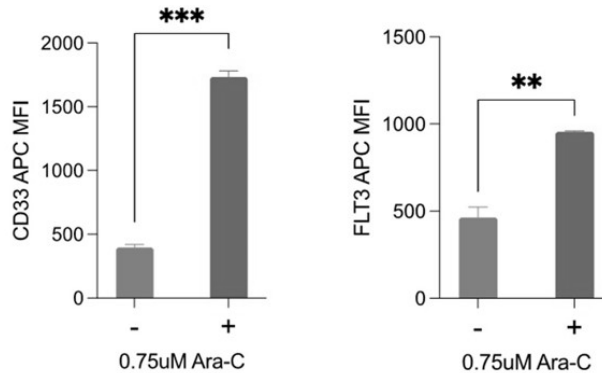
In December 2023, our IND application for evaluation of SENTI-202 in patients with hematologic malignancies was cleared by the FDA, and we expect to start dosing patients in a Phase 1 clinical trial in the second quarter of 2024.

Our Phase 1 clinical trial aims to evaluate SENTI-202 in patients with relapsed/refractory CD33 and/or FLT3 positive hematologic malignancies including AML. Key features of the study design that are intended to increase the potential for deep, durable remissions for AML patients include:

- **Disease-specific lymphodepletion (“LD”)**: We plan to administer three doses of SENTI-202 following a disease-specific LD regimen known as fludarabine (flu) and cytarabine (ara-C), or flu/ara-C. The use of flu/ara-C is an NCCN Category 2a chemotherapy regimen for patients with relapse-refractory AML. In large Phase 3 randomized trials, where flu/ara-C with or without idarubicin, another chemotherapeutic agent approved for AML, has been administered as control arm chemotherapy, the regimen was well tolerated with mild non-hematologic toxicities, most commonly mucositis, and true CR rates of ~10% (cumulative CR rates including CR with incomplete bone marrow recovery of ~ 20%) have been reported. Flu/ara-C LD conditioning followed by multiple doses of NK cell therapies have been well-tolerated, with CR rates in the range of 50-60%. Further, preclinical data reveals that pre-treatment with ara-C increases CD33 and FLT3 expression of a CD33/FLT3-negative AML cell line (e.g., KG-1a), leading to enhanced SENTI-202-mediated cytotoxicity in vitro, which could contribute to potential clinical synergistic anti-AML activity along with the additive debulking of AML blasts prior to administering SENTI-202 to potentially achieve deep responses.

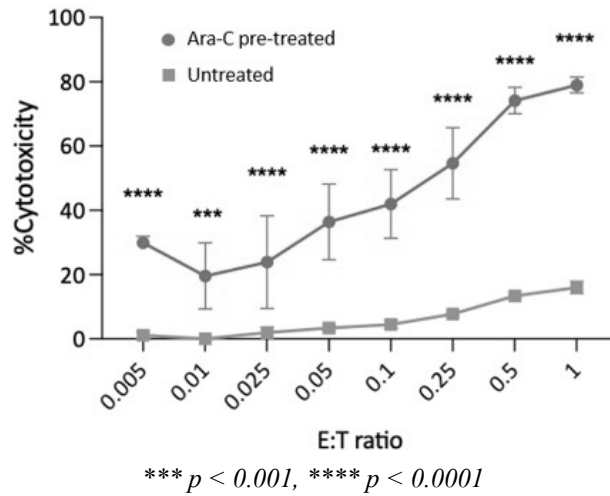
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72h Ara-C Treatment Significantly Upregulated CD33 and FLT3 Expression in KG-1a Cells

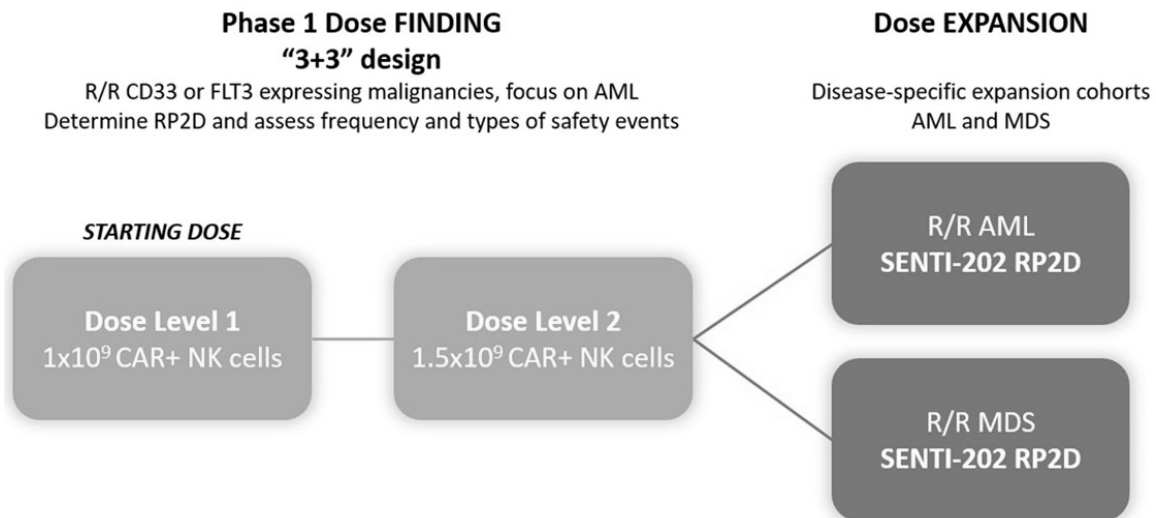


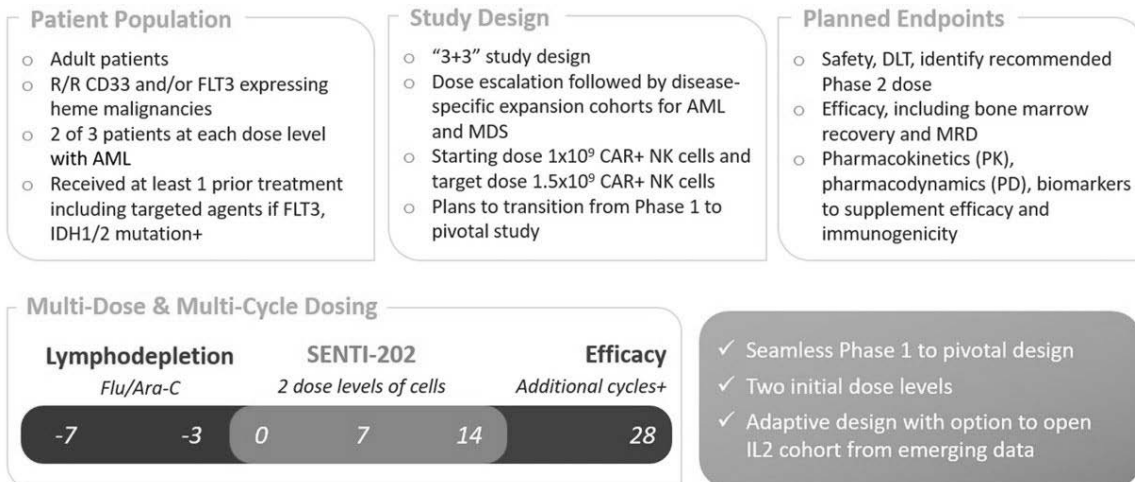
**** $p < 0.01$, *** $p < 0.001$**

Ara-C Pre-Treated KG-1a Cells Sensitized to SENTI-202-Mediated Cytotoxicity



- Multi-dose and multi-cycle administration:** The starting dose of SENTI-202, as approved by the FDA in our IND, will be 1 billion CAR-NK cells. The Phase 1 study will evaluate three doses of 1 billion CAR-NK cells, each dose administered a week apart, after LD, followed by bone marrow assessment at the end of the 4th week (and these 4 weeks make up one cycle). At the end of a cycle, we will evaluate both efficacy and safety. Patients may be eligible to receive additional such cycles based on both tumor response and tolerability of treatment. The study will evaluate both 1 billion and 1.5 billion CAR-NK cell doses and evaluate efficacy and pharmacodynamic markers in addition to standard Phase 1 objectives of safety, pharmacokinetics and dose finding.
- Adaptive design and seamless transition to pivotal:** The Phase 1 study design also includes the ability to evaluate an ultra-low dose IL2 cohort, which could further augment SENTI-202 activity and persistence. The study is designed to seamlessly expand and rapidly transition to a pivotal study assuming the data supports the expansion.



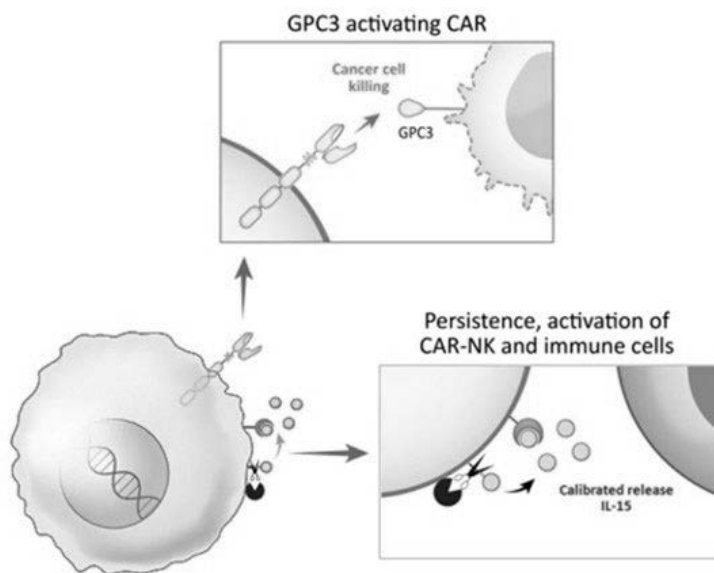


SENTI-301A for the Potential Treatment of HCC and Other Solid Tumors

Overview

Our product program SENTI-301A is a multi-armed off-the-shelf healthy donor derived CAR-NK cell therapy designed for the treatment of advanced GPC3 positive tumors. In partnership with Celest Therapeutics, a product candidate for the SENTI-301A program is in clinical development in China in patients with hepatocellular carcinoma (“HCC”). We anticipate that Celest Therapeutics will begin dosing patients with product candidate SENTI-301A in the second quarter of 2024. This program requires engineering NK cells with a CAR to target GPC3, which is highly expressed in 70% to 90% of HCCs and has low or no expression on normal adult tissues. SENTI-301A is armed with our proprietary crIL-15 gene circuit, intended to simultaneously stimulate surrounding immune cells and promote NK cell expansion, persistence, and tumor killing. The cell source for SENTI-301A is peripheral blood NK cells.

The following figure illustrates the design of SENTI-301A.



Hepatocellular Carcinoma: an Unmet Medical Need

HCC accounts for approximately 90% of primary liver cancers and represents a large unmet medical need due to the lack of effective treatment options. Globally, it is the sixth most diagnosed cancer, and the fourth leading cause of cancer deaths. In the United States, the rate of death from liver cancer increased by 43% from 7.2 to 10.3 deaths per 100,000 people between 2000 and 2016. Frequently, HCC develops in patients with liver disease such as chronic hepatitis B or C virus, alcoholic liver disease or non-alcoholic steatohepatitis. In China, where we have partnered with Celest Therapeutics, there were approximately 400,000 new cases of HCC in 2020, accounting for approximately 65% of worldwide liver cancer diagnoses.

Available therapies are only modestly efficacious and the mortality rate in advanced HCC remains high despite recent improvements in treatment options. The most effective therapy currently available for advanced HCC is atezolizumab plus bevacizumab combination therapy for first line treatment with a 28% objective response rate and a 7% complete response rate.

SENTI-301A Approach to Advanced HCC

SENTI-301A off-the-shelf NK cells are engineered to incorporate multiple anti-tumor activities to achieve a multi-armed attack on solid tumors.

Specifically, SENTI-301A includes:

1. An aCAR that targets GPC3, a highly expressed antigen in HCC and that has low or no expression on normal adult tissues.
2. crIL-15 to simultaneously stimulate surrounding immune cells and promote NK cell expansion, and persistence, and tumor killing.

GPC3 is a TAA expressed in approximately 70% to 90% of human HCCs and in 29-54% of other solid tumors (including lung, ovarian, and thyroid), but not expressed in healthy liver tissue or other human organs after birth. GPC3 has previously been clinically evaluated as a therapeutic target for immunotherapy in HCC. GPC3 is also a histologic and serum clinical marker for HCC and its expression has been associated with poor prognosis. Functionally, GPC3 is associated with the control of cell division and growth regulation. We engineered GPC3 CAR constructs to redirect NK-mediated cytotoxicity against advanced HCC using a GPC3 binder that associates to the membrane proximal region of the GPC3 protein.

IL-15 has been shown to improve NK cell persistence *in vivo* and maintain cytotoxicity. Our proprietary crIL-15 gene circuit is designed to promote NK cell expansion, persistence, and tumor killing. We believe that the ability of crIL-15 to secrete active IL-15 into the TME in a calibrated fashion should also enable stimulation of endogenous immune cells within the tumor microenvironment in solid tumor settings.

Development Plan and Key Next Steps for SENTI-301A

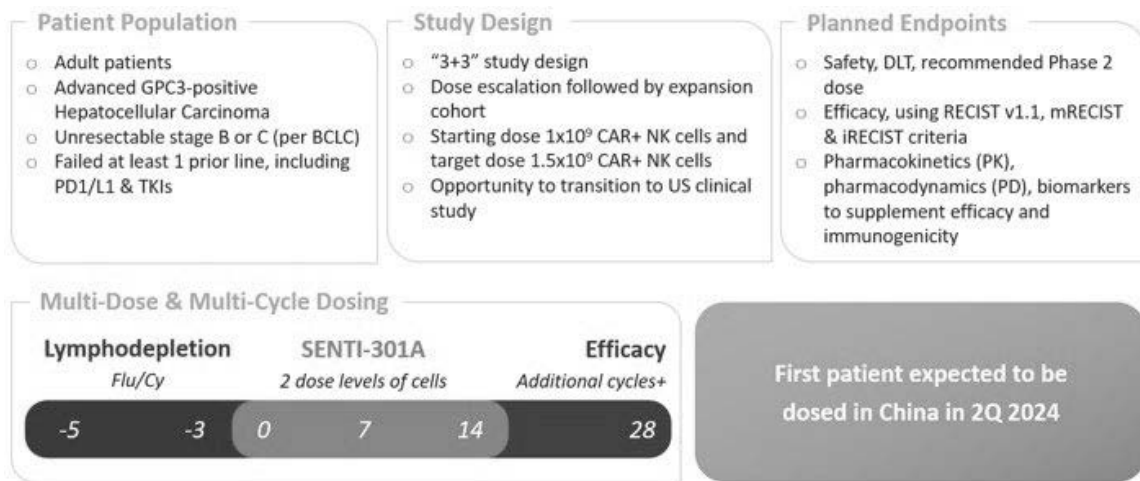
In November 2023, we announced our strategic collaboration with Celest Therapeutics for the clinical development of product candidate SENTI-301A to treat solid tumors in China.

Through this collaboration, Celest Therapeutics will lead clinical development, operations, and manufacturing for the advancement of product candidate SENTI-301A with technical support from Senti. Celest Therapeutics plans to enroll patients initially through a pilot trial in mainland China and expects to enroll the first patient in the second quarter of 2024. Celest Therapeutics and Senti have the option to expand clinical development of SENTI-301A to Hong Kong, Macau and Taiwan. We retain all commercialization rights outside of mainland China, Hong Kong, Macau, and Taiwan for SENTI-301A.

The pilot study aims to evaluate the product candidate SENTI-301A in patients with GPC3 positive advanced HCC in China. Key features of the study design include:

- **Lymphodepletion (LD) before product administration:** Celest Therapeutics plans to administer 3 doses of product candidate SENTI-301A following fludarabine/cyclophosphamide lymphodepletion which has been widely used to support the expansion of NK cells in prior clinical trials.

- **Multi-dose and multi-cycle administration:** The starting dose of product candidate SENTI-301A will be 1 billion CAR NK cells. The pilot study will evaluate three doses of 1 billion CAR-NK cells each. Each individual dose will be administered one week after LD. After treatment, at the end of the fourth week, tumor response assessment will be performed utilizing imaging and biomarkers. At the end of a cycle, Celest Therapeutics will evaluate both efficacy and safety. Patients may be eligible to receive additional cycles based on both tumor response and tolerability of treatment. The study will evaluate 2 dose levels of cells and evaluate efficacy and pharmacodynamic markers in addition to standard Phase 1 objectives of safety, pharmacokinetics and dose finding.



Our CAR-NK Cell Source

Our preferred cell source for SENTI-202 and SENTI-301A, our off-the-shelf CAR-NK cell product programs, is peripheral blood NK cells because it allows us to immediately leverage an established supply chain, a mature GMP process, and extensive clinical experience to develop our next generation CAR-NK cell therapies as described below.

Natural killer (“NK”) cells are an integral part of the innate immune system and comprise 5 to 20% of circulating lymphocytes. They play a key immune surveillance role by recognizing and killing malignantly or virally transformed cells by directed release of lytic granules or by inducing death receptor-mediated apoptosis. Unlike T cells, NK cells possess intrinsic or endogenous anti-cancer activity without engineering or specific antigen priming. NK cells sample potential target cells on a cell-by-cell basis to recognize transformed cells based on the balance of activating and inhibitory signals received by the NK cell from the individual target cell. Other key differences of NK cells compared to T cells, which we believe make NK cells attractive candidates as cellular backbones for novel anti-cancer therapies, include:

- Lack of explosive proliferation and outpouring of cytokines when exposed to target cells, have shown to result in an improved safety profile and to allow repeat dosing due to a general lack of chimeric antigen receptor (“CAR”) T cell-like adverse events such as cytokine release syndrome (“CRS”) or immune effector cell-associated neurotoxicity syndrome (“ICANS”),
- Lack of a T cell receptor (“TCR”) in NK cells have shown to result in inability to initiate graft-versus-host disease (GvHD), enabling NK cells to be used in allogeneic therapies without need for additional genetic manipulation, and
- Allogeneic NK cells have shown to have a finite lifespan of approximately 2-3 weeks in patients when administered after LD due to clearance from host immune cell recovery, leading to decreased potential for long term side effects such as second primary malignancies.

Over 900 patients have safely received NK cell-based therapies since 2005. This includes over 800 patients across more than 30 single institution academic studies who received non-engineered allogeneic NK cell therapy, the majority from healthy adult donors, and nearly 100 patients who have received CAR NK cells via single and multi-center early phase trials.

NK cell products are generally well tolerated and show clinical efficacy as a stand-alone treatment, with 20-60% CR rate on average across a wide variety of oncological conditions, including in patients with AML. This clinical activity was enhanced under several different conditions: 1) when the NK cells had been engineered with CARs. 2) cultured with cytokines. 3) after ‘activation’ by co-culturing with K562 cell lines (themselves modified to express cytokines), 4) when NK cell doses increased, and 5) for AML patients when fludarabine/ara-C (flu/ara-C) LD was used as lymphodepleting conditioning. Key limitations of the clinical experience with NK cells in AML patients include limited persistence of the infused cells, short durability of the observed responses, and immune evasion of LSCs. Other challenges include manufacturing, with culturing and cryopreserving NK cells precluding higher or multiple doses.

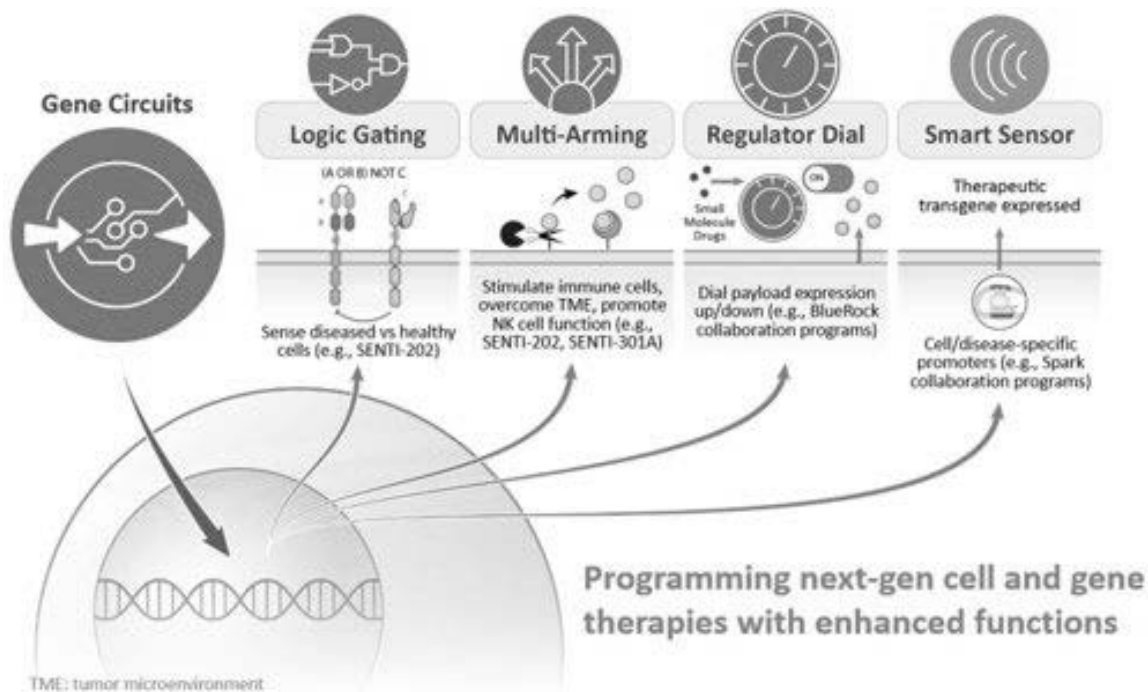
We also believe that our proprietary donor selection process could confer us unique advantages. The process begins with healthy donors screened by our vendor(s) via their protocol(s) for various viruses and ability to undergo leukapheresis. Senti then performs a manufacturing suitability assessment of a research use only leukopak from the healthy donors selected by the vendor(s). The results are then utilized to specify which healthy donors we would like to request for clinical grade leukopaks to be used in our GMP manufacturing process.

Gene Circuits Could Enhance Precision, Control, and Activity of Cell & Gene Therapies

Our Gene Circuit Solutions

In our pursuit to create a new generation of smarter medicines, we have built a toolbox of proprietary gene circuit platform technologies that we believe may enhance the risk benefit paradigm of cell and gene therapy products. Four core categories of gene circuits comprise our gene circuit platform: Multi-Arming, Logic Gating, Regulator Dials and Smart Sensors. Each of our gene circuit platform technologies is designed to confer greater clinical and therapeutic activity, precision and control to cell and gene therapies.

We believe that our core gene circuit platform technologies are the foundation of smarter medicines that are designed to precisely kill diseased cells, spare healthy cells, increase specificity to target cells and control the expression of drugs even after administration. These technologies can be categorized as follows:



Multi-Arming: Multi-Arming gene circuits are designed to incorporate multiple payloads into a single cell or gene therapy product. These gene circuits are intended to activate various biological pathways in complementary ways to prevent diseases from evading single-target treatments, and thereby potentially improve treatment efficacy. Existing combination therapies that target complex diseases require the application of multiple individual drugs, which is difficult due to research, clinical development, regulatory and pharmacology barriers.



Logic Gating: Logic Gating gene circuits are designed to enable cell and gene therapies to control their therapeutic activity in response to the presence or absence of multiple disease biomarkers. Below are examples of Logic Gates applied to cancer, although Logic Gating may also be applied to various other disease indications.



NOT GATE: NOT GATE gene circuits are designed to widen the therapeutic window by enabling effective killing of cancer cells while preserving healthy cells. The NOT GATE functions by recognizing Protective Antigens (PAs), or antigens that are selectively expressed on healthy cells and not on cancer cells, thus limiting on-target, off-tumor killing. By protecting healthy cells, the NOT GATE has the potential to enable more effective on-target, on-tumor killing of tumor cells that express TAAs. Generally, existing cancer drugs target only a single antigen, which means they can only be effectively and safely used in situations where that antigen is uniquely expressed on tumors and not in healthy cells, or where the on-target, off-tumor effects are tolerable.



OR GATE: OR GATE gene circuits are designed to address tumor heterogeneity and limit antigen escape. The OR GATE functions by killing tumor cells that express any one of multiple antigens. Generally, current medicines are unable to address more than one target at a time and are thus susceptible to tumor evasion.



Regulator Dial: Regulator Dial gene circuits are designed to enable the precise tuning of therapeutic activity from a cell or gene therapy product. For example, this can be implemented by regulating therapeutic payload expression in response to varying concentrations of FDA-approved drugs. Regulator Dials are expected to enable the exogenous regulation of next-generation cell and gene therapies even after they have been delivered in vivo. Existing cell and gene therapies cannot be modulated once they have been delivered into patients.



Smart Sensor: A Smart Sensor is a gene circuit, or combination of gene circuits, designed to precisely detect distinct cell types or disease environments, and thus distinguish between the “disease state” and “healthy state.” For example, Smart Sensors can be engineered to detect whether certain conditions, or disease biomarkers, are present before responding with a specific therapeutic response. Conventional medicines are generally unable to dynamically change their behavior in response to cell or disease specific conditions.

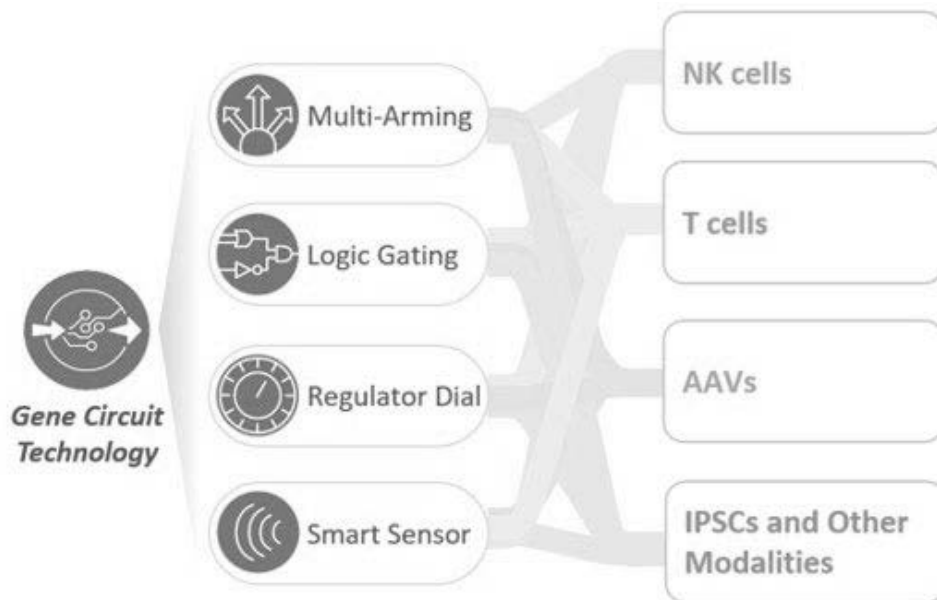
We Believe Our Gene Circuits May Have Broad Applicability in Multiple Treatment Modalities and Disease Areas

We believe that our gene circuit platform may have broad applicability across treatment modalities and disease areas, and is also potentially applicable toward engineering optimal efficacy, precision and control into cell or gene-based medicines.

Treatment Modalities: Our gene circuit platform technologies are designed to be applied in a modality-agnostic manner, with applicability to NK cells, T cells, TILs, stem cells including iPSCs and HSCs, *in vivo* gene therapy such as AAV, and mRNA. We have conducted research in multiple cell types and vector types, and the initial focus of our internal pipeline utilizes off-the-shelf CAR-NK cells outfitted with Gene Circuit technologies in oncology indications.

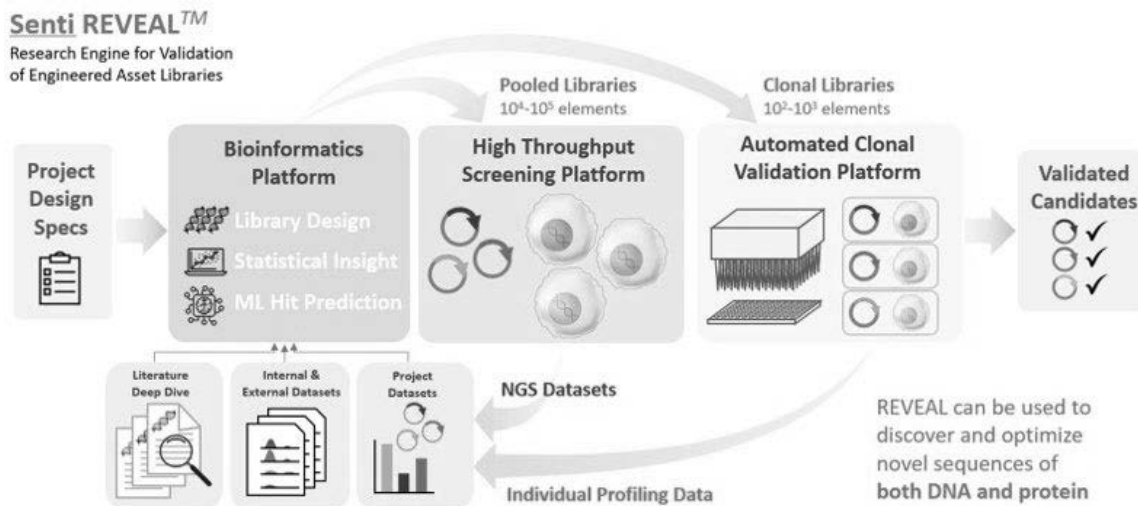
Disease Areas: Our gene circuits can be customized to address many aspects of disease biology. We have demonstrated and published applications of gene circuits across many different *in vivo* disease models. Thus, we believe that our gene circuit platform technologies can be used against a broad range of diseases that span therapeutic areas such as oncology, immunology, genetic diseases, neurology, cardiology, metabolic diseases, ophthalmology and regenerative medicine.

The following figure presents our perspective on how our gene circuit technologies can be utilized across modalities and corresponding therapeutic areas:



Portfolio Expansion Opportunities

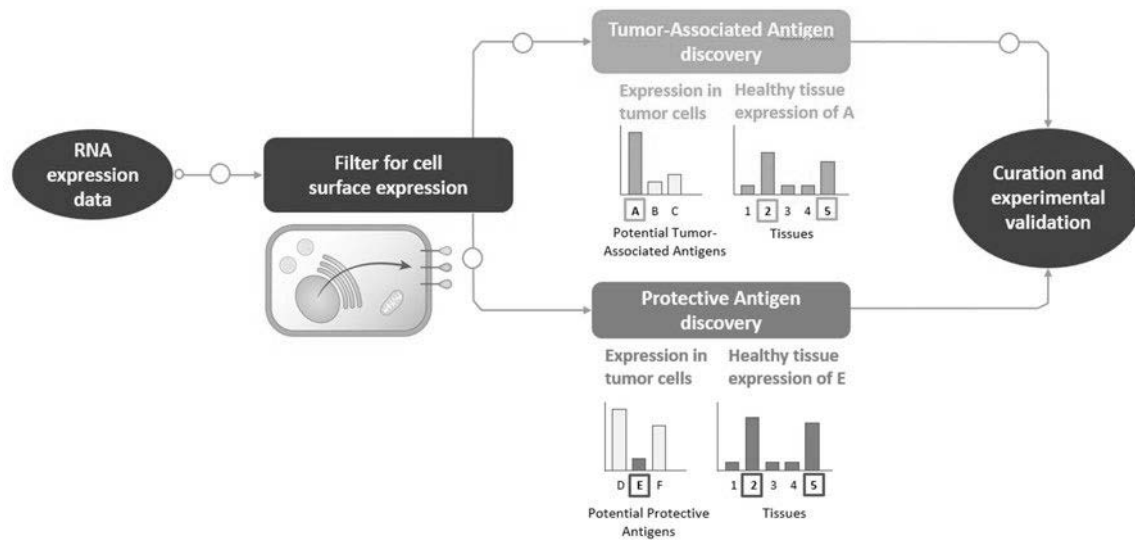
We have developed a proprietary, versatile, and robust internal research engine to enable development and adaptation of our gene circuits to address broad set of new disease and therapeutic modality challenges:



We believe that our REVEAL™ platform enables us to effectively explore innumerable application opportunities for gene circuits and efficiently optimize best-in-class solutions. Opportunities include, but are not limited to: (i) the application of the NOT GATE gene circuit toward new solid and/or liquid tumor CAR-NK or CAR-T cell therapies, (ii) the application of the Multi-Arming gene circuit to enhance and power new solid and/or liquid tumor CAR or TCR based cell therapies (iii) the development of promoters that are multi-fold stronger than current commonly used promoter benchmarks for various cell types, and (iv) cell-type and cell-state specific promoters for gene and cell therapies. We believe our platform can enable the development of multiple product candidates that harness the full breadth of our gene circuit platform beyond Logic Gating and Multi-Arming of CAR or TCR based cell therapies within oncology. Our additional discovery efforts are focused on a diverse set of cell and gene therapy applications outside of oncology. We have entered into collaborations with Spark Therapeutics (subsidiary of Roche Holding AG) for the design of Smart Sensors for disease- and tissue-specific gene therapy, and with Bluerock Therapeutics (subsidiary of Bayer AG) for the use of Smart Sensors and Regulator Dials for regenerative medicines.

Tumor-Associated Antigen and Protective Antigen Paired Discovery Platform

We have developed a proprietary TAA and PA paired discovery platform to select and validate NOT GATE antigen candidates, as shown in the figure below. We have built a generalizable bioinformatics pipeline that uses RNA transcriptomics data to discover and prioritize tumor and healthy tissue PAs. We identify TAAs that are highly expressed in cancer cells with minimal healthy tissue expression (antigen A in figure below). We then identify healthy tissue selective PAs (antigen E in figure below) that can protect those healthy tissues that express the TAAs (tissues 2 and 5 below). This process evaluates differences in PA gene expression in healthy versus tumor tissue. Leads are selected based on the co-expression of TAAs and PAs in healthy tissues, the localization of the PAs to the cell surface, PA topology (presence of extracellular domain) and PA-specific antibody availability. Prioritized TAA and PA pairs are further validated in primary cancer and primary healthy tissue samples. We leveraged this platform to identify PA targets for the SENTI-202 and other internal programs, thus demonstrating our ability to target both liquid and solid tumors. This approach allows us to potentially expand our NOT GATE approach to additional cancer indications in which existing single-target approaches, such as monoclonal antibodies, antibody-drug conjugates and single-target CAR cells, are inadequate due to a lack of specificity for cancer cells.



Manufacturing

In August 2023, we announced the sale of our manufacturing assets and a sublease of our 92,000 square foot manufacturing facility to a private equity group, Celadon Partners, who created a new independent contract manufacturing organization for cell and gene therapy, and synthetic biology biofoundry called GeneFab, LLC (“GeneFab”).

In connection with the transaction, we are entitled to receive total consideration of \$37.8 million before the end of 2025, of which \$18.9 million was due at closing and was netted against prepayment owed by us for manufacturing and research activities to GeneFab. The remaining consideration of \$18.9 million will be received in installments during 2024 and 2025, subject to satisfaction of certain conditions. We also received \$8 million in manufacturing services credit and subleased our 92,000 square foot good manufacturing practice (“cGMP”) facility in Alameda, CA to GeneFab.

The transaction has allowed us to focus on advancing our oncology programs into the clinic. GeneFab will conduct the clinical manufacturing of our CAR-NK pipeline in the United States, including SENTI-202, through a service contract.

Our Material Agreements

Exclusive/Co-Exclusive Patent License Agreement with the National Cancer Institute for FLT3 Technology

In July 2020, we entered into an Exclusive/Co-Exclusive Patent License Agreement, as amended, or the NCI FLT3 Agreement, with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, or the NCI, under which the NCI granted us a worldwide, royalty-bearing, sublicensable license under the NCI’s patent rights related to FLT3-targeting chimeric antigen receptor, or CAR, technology (i) exclusively for the development of a universal or split CAR-based immunotherapy using T-cells or NK cells transduced with lentiviral vectors or other retroviral vectors, depending on the cell type, for the prophylaxis or treatment of cancers expressing FMS-like tyrosine kinase 3, or FLT3, where the CAR construct binds to specific domains and (ii) co-exclusively, with a third party, for the development of a multi-specific FLT3 CAR-based immunotherapy or FLT3-specific regulated or switch or Logic Gated CAR-based immunotherapy using T-cells or NK cells transduced with lentiviral vectors or other retroviral vectors, depending on the cell type, for the prophylaxis or treatment of FLT3-expressing cancers, where the CAR construct contains specific domains, in each case of (i) and (ii), to make and have made, use and have used, sell and have sold, offer to sell and import products covered by the licensed patent rights and to

practice and have practiced processes covered by the licensed patent rights. In addition to the co-exclusive rights held by a third party, the foregoing license is subject to (a) certain rights of the United States government, including an irrevocable, non-exclusive, non-transferable, royalty-free license for the government to practice all licensed patent rights throughout the world and (b) the NCI's reserved rights to grant a non-exclusive license to practice the licensed patent rights for purposes of internal research (and not for purposes of commercial manufacture or distribution) at an academic or corporate facility.

Pursuant to the NCI FLT3 Agreement, we must use commercially reasonable efforts to adhere to a commercial development plan, including by achieving certain specified development and regulatory milestones by certain dates, provided that we may request to extend the timelines of such milestones, which the NCI shall not unreasonably deny if the request is supported by a reasonable showing of our diligent performance under the commercial development plan. Upon the first commercial sale of a licensed product or process, we must also use commercially reasonable efforts to make the licensed product or process reasonably accessible to the United States public.

In consideration for the rights granted to us under the NCI FLT3 Agreement, we paid the NCI a one-time, non-refundable license issue fee of \$75,000, and are required to pay the NCI a minimum flat annual royalty fee of a dollar amount in the low five digits. We are also obligated to pay the NCI certain development, regulatory and commercial milestone payments of up to an aggregate of \$4.6 million for the first licensed product to achieve the applicable event. We will also be required to pay the NCI a tiered royalty in the low-single digit percentages on net sales of each licensed product by us and our sublicensees, subject to specified reductions and offsets, including against the minimum annual royalty payments. Further, the NCI is entitled to receive a portion of the amounts – excluding royalties and certain payments – we receive as a result of the grant of a sublicense under the rights granted under the NCI FLT3 Agreement at a percentage ranging from the low-single digits to low-double digits, depending on the stage of development at which the sublicense is granted. Additionally, we are obligated to pay for a portion of patent expenses that NCI incurred with respect to the licensed patent rights.

The NCI FLT3 Agreement will expire, on a licensed product-by-licensed product and country-by-country basis, on the expiration of all licensed patent rights that claim the applicable licensed product in the applicable country. Licensed patent rights are currently expected to expire in 2037, absent patent term extension or adjustment. We may terminate the NCI FLT3 Agreement in its entirety or with respect to a country for any reason by providing 60 days' prior written notice to the NCI. The NCI may terminate the NCI FLT3 Agreement if (i) we breach any material obligations under the NCI FLT3 Agreement and fail to cure such breach within 90 days after receiving written notice thereof, or (ii) if the NCI reasonably determines that (a) we are not using commercially reasonable efforts to execute the commercial development plan, including the milestones specified therein, (b) we have willfully made a false statement or omitted a material fact in our license application or any report to the NCI, (c) we have committed a material breach of a covenant or agreement to the NCI, (d) we are not keeping the licensed products or licensed services reasonably available to the public after commercial use commences, or (e) we cannot reasonably justify a failure to comply with the domestic production requirement, in each case of (a) through (e), where we fail to alleviate the NCI's concerns in 90 days. Additionally, the NCI reserves the right to terminate or modify the NCI FLT3 Agreement if the NCI determines that such action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by us.

Exclusive Patent License Agreement with the National Cancer Institute for CD33 Technology

In May 2021, we entered into an Exclusive Patent License Agreement, or the NCI CD33 Agreement, with the U.S. Department of Health and Human Services, as represented by the NCI, under which the NCI granted us an exclusive, royalty-bearing, sublicensable, worldwide license under the NCI's patent rights related to CD33 targeting CAR technology to make and have made, use and have used, sell and have sold, offer to sell and import products covered by the licensed patent rights and to practice and have practiced processes covered by the licensed patent rights, for the development of a CD33-specific logic-gated CAR-based immunotherapy using autologous human T cells transduced with lentiviral vectors or off-the-shelf human NK cells transduced with retroviral vectors for the prophylaxis or treatment of CD33-expressing cancers. The foregoing license is subject to (i) certain rights of the United States government, including an irrevocable, non-exclusive, nontransferable, royalty-free license for the government to practice all licensed patent rights throughout the world and (ii) the NCI's reserved rights to grant a

non-exclusive license to practice the licensed patent rights for purposes of internal research (and not for purposes of commercial manufacture or distribution) at an academic or corporate facility.

Pursuant to the NCI CD33 Agreement, we must use commercially reasonable efforts to adhere to a commercial development plan, including by achieving certain specified development and regulatory milestones by certain dates, provided that we may request to extend the timelines of such milestones, which the NCI shall not unreasonably deny if the request is supported by a reasonable showing of our diligent performance under the commercial development plan. Upon the first commercial sale of a licensed product or process, we must also use commercially reasonable efforts to make the licensed product or process reasonably accessible to the United States public.

In consideration for the rights granted to us under the NCI CD33 Agreement, we paid the NCI a one-time, non-refundable license issue fee of \$150,000, and are required to pay the NCI a minimum flat annual royalty fee of a dollar amount in the low five digits. We are obligated to pay the NCI certain development, regulatory and commercial milestone payments of an aggregate of \$3.5 million for the first licensed product to achieve the applicable events. We will also be required to pay the NCI a flat royalty in the low single-digit percentages on net sales of each licensed product by us and our sublicensees, subject to specified reductions and offsets, including against the minimum annual royalty payments. Further, the NCI is entitled to receive a portion of the amounts—excluding royalties and certain payments—we receive as a result of the grant of a sublicense under the rights granted under the NCI CD33 Agreement at a percentage ranging from the low-single digits to low-double digits, depending on the stage of development at which the sublicense is granted. Additionally, we are obligated to pay for patent expenses that NCI incurred with respect to the licensed patent rights.

The NCI CD33 Agreement will expire, on a licensed product-by-licensed product and country-by-country basis, on the expiration of all licensed patent rights that claim the applicable licensed product in the applicable country. Licensed patent rights are currently expected to expire in 2039, absent any patent term extension or adjustment. We may terminate the NCI CD33 Agreement in its entirety or with respect to a country for any reason by providing 60 days' prior written notice to the NCI. The NCI may terminate the NCI CD33 Agreement if (i) we breach any material obligations under the NCI CD33 Agreement and fail to cure such breach within 90 days after receiving written notice thereof, or (ii) if the NCI reasonably determines that (a) we are not executing the commercial development plan, including the milestones specified therein, (b) we have willfully made a false statement or omitted a material fact in our license application or any report to the NCI, (c) we have committed a material breach of a covenant or agreement to the NCI, (d) we are not keeping the licensed products or licensed services reasonably available to the public after commercial use commences, (e) we cannot reasonably satisfy unmet health and safety needs, (f) we cannot reasonably justify a failure to comply with the domestic production requirement or (g) we have been found by a court to have violated antitrust laws in connection with our performance under the NCI CD33 Agreement, in each case of (a) through (f), where we fail to alleviate the NCI's concerns in 90 days. Additionally, the NCI reserves the right to terminate or modify the NCI CD33 Agreement if the NCI determines that such action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by us.

Research Collaboration and License Agreement with Spark Therapeutics, Inc.

In April 2021, we entered into a Research Collaboration and License Agreement, or the Spark Agreement, with Spark Therapeutics. Under the Spark Agreement, we engaged in a collaborative research program with Spark Therapeutics to design, build and test synthetic promoters that are intended to have each one of five sets of desired characteristics, or promoter profiles. Spark Therapeutics is obligated to reimburse us for our costs and expenses incurred in connection with the conduct of the research program. Upon completion of work under the research program for a particular promoter profile, Spark Therapeutics may select and designate, subject to a specified maximum, a certain number of synthetic promoters that are designed, built and tested or identified by us under the research program with respect to such promoter profiles as optioned promoters. On a promoter profile-by-promoter-profile basis, for each optioned promoters, Spark Therapeutics will have the right to obtain an exclusive, royalty-bearing, sublicensable, worldwide license under our intellectual property rights to develop, manufacture, commercialize and otherwise exploit, for the cure, treatment, palliation, prevention or diagnosis of specified indications, or a licensed field, *in vivo* gene therapy products incorporating such applicable optioned promoter with respect to such promoter profile and is directed towards specific cell types in the central nervous system, eye, or

liver. Spark Therapeutics may exercise its option for any optioned promoter prior to the expiration of the applicable evaluation period.

After exercise of an option, Spark Therapeutics will be responsible for all development, manufacture, commercialization and exploitation in the licensed field, at its own cost and expense, of all *in vivo* gene therapy products containing an applicable licensed promoter, and we will retain the right to develop, manufacture, commercialize and exploit other products that incorporate the licensed promoters as well as *in vivo* gene therapy products that incorporate the licensed promoters for uses outside the licensed field. If Spark Therapeutics does not exercise an option for a particular promoter profile prior to the expiration of the evaluation period for such promoter profile, we will retain all rights to the synthetic promoters developed under the Spark Agreement without any further obligations to Spark Therapeutics for such promoter profile.

Pursuant to the Spark Agreement, we received an upfront payment from Spark Therapeutics of \$3 million. If Spark Therapeutics exercises an option for a particular promoter profile, it will be required to pay us an option exercise fee in the low to mid-single digit millions. For each licensed promoter-containing *in vivo* gene therapy product, or licensed product, developed and commercialized by Spark Therapeutics or its affiliates or sublicensees, we are eligible to receive development, regulatory and commercialization milestone payments from Spark Therapeutics up to an aggregate dollar amount in the mid teens millions, and sales milestone payments from Spark Therapeutics up to an aggregate dollar amount in the low hundred millions. In total, we are potentially eligible to receive upfront, opt-in and milestone payments exceeding \$645 million if Spark Therapeutics exercises its options for all five promoter profiles and Spark Therapeutics, its affiliates and its sublicensees successfully develop and commercialize five licensed products; we will be eligible to receive additional milestone payments if additional licensed products are developed and commercialized by Spark Therapeutics, its affiliates and its sublicensees. Further, Spark Therapeutics will be obligated to pay us royalties in the low-single digits percentage on net sales of each licensed product sold by Spark Therapeutics, its affiliates and its sublicensees, subject to specified reductions and offsets. Spark Therapeutics's obligation to pay royalties to us will expire for each licensed product when certain licensed patents and regulatory exclusivities have expired in the country of sale and a minimum number of years has elapsed since the first commercial sale of such licensed product in such country. The Spark Agreement will expire at the end of the last evaluation period if Spark Therapeutics does not exercise any of its options. If Spark Therapeutics exercises at least one option, then the Spark Agreement will expire, on a licensed product-by- licensed product and country-by-country basis, upon the expiration of Spark Therapeutics's royalty obligation for such licensed product in such country. Spark Therapeutics may terminate the Spark Agreement in its entirety, or on a promoter profile-by-promoter profile or licensed promoter-by-licensed promoter basis, following a specified notice period. Either party may terminate the Spark Agreement in its entirety or in part if the other party fails to cure its material breach of the Spark Agreement within a specified cure period, or immediately if the other party becomes bankrupt or insolvent. We may terminate the Spark Agreement if Spark Therapeutics or any of its affiliates commences any action challenging the validity or enforceability of the licensed patents, other than in certain specified circumstances, or if Spark Therapeutics's sublicensee challenges our licensed patents, under certain specified circumstances.

Collaboration and Option Agreement with BlueRock Therapeutics LP

In May 2021, we entered into a Collaboration and Option Agreement, or the BlueRock Agreement, with BlueRock Therapeutics LP, or BlueRock. BlueRock is a wholly-owned subsidiary of Bayer Healthcare LLC. Bayer Healthcare LLC's parent company is Bayer AG, which served as the lead investor in our Series B financing through its Leaps by Bayer unit. Under the BlueRock Agreement, we have engaged in three collaboration programs with BlueRock to research and develop gene circuits that have specified functions. We are responsible for up to \$10 million in costs and expenses incurred in connection with our conduct of research activities under an agreed-upon research plan. If the parties mutually agree to add new research activities to the research plan, then BlueRock will be obligated to reimburse us for the costs and expenses that we incur in connection with the agreed-upon additional research activities that, together with costs and expenses incurred under the initial research plan, exceed \$10 million. We have not yet received any payment from BlueRock under the BlueRock Agreement and we do not have any obligations to make any payments to BlueRock under the BlueRock Agreement. We are obligated to use commercially reasonable efforts to conduct the research activities assigned to us under the research plan. If we materially breach that obligation and do not cure it within a specified period, BlueRock will have the right to receive a transfer of technology and perform the remainder of the research plan at its own expense.

Upon completion of work under a research plan for a collaboration program, the joint steering committee established by the parties will identify, subject to a specified maximum, a number of gene circuits per collaboration program, or option gene circuits, that have been successfully developed under such collaboration program. We have granted to BlueRock an option, on a collaboration program-by-collaboration program basis, to obtain an exclusive or non-exclusive license under our intellectual property rights to develop, manufacture and commercialize, for the prevention, treatment or palliation of specified indications, or a licensed field, cell therapy products that contain cells of specified types that incorporate an option gene circuit from such collaboration program or a closely related derivative gene circuit. For each collaboration program, BlueRock may conduct evaluation activities on the option gene circuits from such collaboration program to determine whether to exercise its option, and BlueRock may exercise its option to such option gene circuits together with certain closely related derivative gene circuits, or licensed gene circuits, prior to the expiration of a certain time period, or the option exercise period, which includes a minimum amount of time after the expiration of the three-year research term, delivery of a data package to BlueRock, and completion of a transfer of technology to enable BlueRock's evaluation activities, whichever happens last. If BlueRock exercises its option for a collaboration program, the parties shall negotiate the financial terms, which will be within certain pre-agreed parameters and may be determined by baseball arbitration if the parties do not reach agreement within the specified negotiation period, and enter into an otherwise agreed-upon written license agreement, or a commercial license. If the parties enter into a commercial license, BlueRock will be responsible, at its sole expense, for the development, manufacture and commercialization, in the applicable licensed field, of cell therapy products containing cells of an applicable type that incorporate an applicable licensed gene circuit, and we will be eligible to receive from BlueRock development, regulatory and commercialization milestone payments, in amounts to be agreed-upon before entry into the commercial license, and royalties, subject to negotiation, equal to low single digit percentages of net sales of applicable cell therapy products sold by BlueRock, its affiliates and its sublicensees, subject to specified reductions and offsets. If BlueRock does not exercise its option for a collaboration program prior to the expiration of the applicable option exercise period, then we will retain all rights to the gene circuits developed under such collaboration program without any further obligations to BlueRock.

For each collaboration program, we are obligated to work exclusively with BlueRock on the development, manufacture and commercialization, in the applicable licensed field, of cell therapy products that contain cells of specified types that incorporate the specific type of gene circuit for such collaboration programs. The end date for this exclusivity obligation for each collaboration program will depend upon whether BlueRock exercises its option for such collaboration program and, if it does, whether the parties enter into a commercial license for such collaboration program. If BlueRock does not exercise its option, then it will end on the expiration of the applicable option exercise period. If BlueRock exercises its option but the parties do not enter into a commercial license, then it will end after a specified time following expiration of the applicable negotiation or baseball arbitration period for the commercial license. If BlueRock exercises its option and the parties enter into a commercial license, then it will end a certain amount of time after the later of completion of research activities or execution of the commercial license.

In addition to the option described above, we granted a right of first negotiation to BlueRock, on a collaboration program-by-collaboration program basis, to obtain a license under our intellectual property rights to research, develop, manufacture and commercialize, for the prevention, treatment or palliation of a specified disease area, or the negotiation field, cell therapy products containing cells of a specified type, or the negotiation cells, that incorporate an applicable efficacy gene circuit developed under such collaboration program. This right of first negotiation does not overlap with the option described above because it pertains to different combinations of fields, cell types and gene circuits. Starting from the effective date of the BlueRock Agreement and, on a collaboration program-by-collaboration program basis, continuing for twelve months or, if later, until the completion of a certain portion of the research plan for such collaboration program, we are obligated to work exclusively with BlueRock on the development, manufacture and commercialization, in the negotiation field, of cell therapy products containing negotiation cells that incorporate the specific type of gene circuit for such collaboration program.

The BlueRock Agreement will expire, on a collaboration program-by-collaboration program basis, upon the earliest of the expiration of the option exercise period for such collaboration program, the effective date of the commercial license, the expiration of the applicable negotiation or baseball arbitration period for the commercial license, or the date the parties mutually agree to cease negotiations for the commercial license. Such expiration shall occur no later than January 2026 unless the parties mutually agree to extend the research term. BlueRock may

terminate the BlueRock Agreement in its entirety, or on a collaboration program-by-collaboration program basis, following a specified notice period. Either party may terminate the BlueRock Agreement if the other party fails to cure its material breach of the BlueRock Agreement within a specified cure period, or immediately if the other party becomes bankrupt or insolvent. We may terminate the BlueRock Agreement if BlueRock or any of its affiliates commences any action challenging the validity or enforceability of our patents, other than in certain specified circumstances, or if BlueRock's sublicensee challenges our patents under certain specified circumstances.

National Cancer Institute (NCI) Contract to Support Development of SENTI-202 in Acute Myeloid Leukemia

In September 2021, we were awarded funding from the National Cancer Institute in the form of a Small Business Innovation Research ("SBIR") contract to support further development of SENTI-202 for AML towards clinical development. The Direct to Phase II SBIR contract provided funding over two years from the NCI of the National Institutes of Health ("NIH") and is titled: "Logic-Gated Chimeric Antigen Receptor- Natural Killer Cell Therapy for Acute Myeloid Leukemia." The period of funding and performance under this SBIR contract ended on July 31, 2023 and we received notice from the NIH that this SBIR contract has been administratively closed on February 26, 2024. As a result of the award of this contract, the SENTI-202 program was funded in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N91021C00026.

Exclusive Patent License Agreement with the National Cancer Institute for GPC3 Technology

In February 2021, we entered into an Exclusive Patent License Agreement, or the NCI GPC3 Agreement, with the U.S. Department of Health and Human Services, as represented by the NCI, under which the NCI granted us an exclusive, royalty-bearing, sublicensable, worldwide license under the NCI's patent rights related to glypican-3, or GPC3, targeting CAR technology to make and have made, use and have used, sell and have sold, offer to sell and import products covered by the licensed patent rights and to practice and have practiced processes covered by the licensed patent rights, for the development, production and commercialization of a monospecific CAR-based immunotherapy for the prophylaxis and treatment of GPC3 expressing human cancers using unmodified, off-the-shelf natural killer cells transduced with a viral vector that expresses a CAR, and a gene circuit regulating the expression of one or more armoring payloads, specifically excluding the use of autologous T cells or T cells that have been genetically modified to become off-the-shelf. The foregoing license is subject to (i) certain rights of the United States government, including an irrevocable, non-exclusive, nontransferable, royalty-free license for the government to practice all licensed patent rights throughout the world and (ii) the NCI's reserved rights to grant a non-exclusive license to practice the licensed patent rights for purposes of internal research (and not for purposes of commercial manufacture or distribution) at an academic or corporate facility.

The NCI GPC3 Agreement will expire, on a licensed product-by-licensed product and country-by-country basis, on the expiration of all licensed patent rights that claim the applicable licensed product in the applicable country. Licensed patent rights are currently expected to expire in 2033, absent any patent term extension or adjustment. We may terminate the NCI GPC3 Agreement in its entirety or with respect to a country for any reason by providing 60 days' prior written notice to the NCI. The NCI may terminate the NCI GPC3 Agreement if (i) we breach any material obligations under the NCI GPC3 Agreement and fail to cure such breach within 90 days after receiving written notice thereof, or (ii) if the NCI reasonably determines that (a) we are not executing the commercial development plan, including the milestones specified therein, (b) we have willfully made a false statement or omitted a material fact in our license application or any report to the NCI, (c) we have committed a material breach of a covenant or agreement to the NCI, (d) we are not keeping the licensed products or licensed services reasonably available to the public after commercial use commences, (e) we cannot reasonably satisfy unmet health and safety needs, (f) we cannot reasonably justify a failure to comply with the domestic production requirement or (g) we have been found by a court to have violated antitrust laws in connection with our performance under the NCI GPC3 Agreement, in each case of (a) through (f), where we fail to alleviate the NCI's concerns in 90 days. Additionally, the NCI reserves the right to terminate or modify the NCI GPC3 Agreement if the NCI determines that such action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by us.

Framework Agreement with GeneFab, LLC

In August 2023, we completed a transaction with GeneFab, a contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. Under a framework agreement entered into by us and GeneFab, we sold, assigned and transferred rights, title and interest in certain of our assets and contractual rights, including all of our equipment at our facilities in Alameda and certain of our intellectual property related to the schematics for and design of the Alameda facility. We subleased our recently constructed 92,000 square foot current good manufacturing practice facility in Alameda, California to GeneFab which will support the clinical manufacturing of our CAR-NK programs, including SENTI-202. The transaction provided us with additional capital in the form of a note receivable and rights to future manufacturing and research activities and reduced longer term operating expenses. In connection with the transaction, we are entitled to receive total consideration of \$37.8 million before the end of 2025, of which \$18.9 million was payable at closing and was netted against prepayment owed by us for manufacturing and research activities to GeneFab under a development and manufacturing services agreement that was separately entered into by us and GeneFab as part of the transaction. The remaining \$18.9 million will be paid to us in installments in 2024 and 2025, subject to satisfaction of certain conditions. The Company determined that the \$18.9 million for future manufacturing and research activities, inclusive of the volume discount provided, was executed at market terms and does not result in any impact to the total consideration received from GeneFab for the disposal of the business.

We also agreed to grant a license to GeneFab under certain of our intellectual property rights to conduct manufacturing services and to research, develop, manufacture and commercialize products outside of oncology, pursuant to a license agreement that is still under negotiation as of March 2024.

GeneFab was provided an option to purchase up to 19,633,444 shares (i.e. up to \$20.0 million worth) of our common stock at an exercise price of \$1.01867, or the GeneFab Option. The GeneFab Option is exercisable upon the execution of the license agreement, no later than August 7, 2026. The GeneFab Option may be exercised in installments of common stock equal to no more than 19.9% of our outstanding shares of common stock as of the closing date of the transaction.

As additional consideration for the transaction, we entered into a seller economic share agreement with GeneFab, pursuant to which we will be entitled to receive ten percent of the realized gains of GeneFab's parent company arising and resulting from any cash or in-kind distributions from GeneFab in connection with a dividend or sale event, subject to the terms and conditions of the GeneFab Economic Share.

Collaboration and Option Agreement with Celest Therapeutics, (Shanghai) Co. Ltd.

In November 2023, we entered into a Collaboration and Option Agreement, or the Celest Agreement, with Celest Therapeutics. Under the Celest Agreement, we agreed to collaborate with Celest Therapeutics for Celest Therapeutics to carry out an investigator-initiated trial ("IIT") of the SENTI-301A program in mainland China with certain technical support from us. Celest Therapeutics will have an exclusive option to obtain an exclusive, royalty-bearing, license in mainland China, Hong Kong, Macau, and Taiwan under our intellectual property rights to research, develop, manufacture, commercialize and otherwise exploit an off-the-shelf CAR-NK cell therapy product candidate that consists of NK cells that have been engineered to express our CAR having an antigen binding portion that is directed to GPC3 and our crIL15, such product candidate the SN301A Product. Celest Therapeutics may exercise its option prior to the expiration of a certain time period, or the option exercise period. If Celest Therapeutics exercises its option during the option exercise period, the parties shall negotiate the terms of the license agreement, which will include and be consistent with pre-agreed financial terms, and Celest Therapeutics will be required to pay us an option exercise fee in the mid-single digit millions upon the execution of the license agreement. If the parties enter into a license agreement having terms consistent with the pre-agreed financial terms, we will be eligible to receive certain option exercise fee and milestone payments, in an aggregate amount of \$156.0 million, as well as certain tiered royalty payment.

During a certain time period, or the exclusivity period, we are prohibited from directly or indirectly, exploiting or enabling any third party to research, develop manufacture, commercialize or otherwise exploit in mainland China any off-the-shelf CAR-NK cell therapy having an antigen binding portion of the CAR directed to GPC. If Celest

Therapeutics does not exercise its option, then the exclusivity period will end on the expiration of the option period. If Celest Therapeutics exercises its option, then the exclusivity period will end upon the expiration of the applicable negotiation period for the license agreement or the mutual execution of the license agreement, whichever is earlier. If Celest Therapeutics exercises its option and the parties are unable to execute a mutually agreed license agreement during the negotiation period, then the option will automatically be deemed expired and we will have no further obligation to Celest Therapeutics under the Celest Agreement, except that for a certain time period following the expiration of the negotiation period, Celest Therapeutics will have certain rights if we receive a bona fide offer from a third party for such third party to obtain an exclusive license or similar exclusive rights under our technology to research, develop, manufacture, commercialize or otherwise exploit the SN301A Product in certain territories on certain terms and Celest Therapeutics will have certain rights if we enter into any arrangement with any third party pursuant to which we grant an exclusive license or similar exclusive right under technology to research, develop, manufacture, commercialize or otherwise exploit the SN301A Product in certain territories on certain terms.

The Celest Agreement will expire upon the earliest of the expiration of the option exercise period, the expiration of the negotiation period of the license agreement, or on the date of execution of the license agreement. We may terminate the Celest Agreement if Celest Therapeutics does not proceed to certain IIT preparation stages or if there is a delay to meeting the target date for the IIT initiation and the parties are unable to agree to an extension target date. We may also terminate the Celest Agreement if Celest Therapeutics or any of its affiliates commences any action challenging the validity or enforceability of our patents, other than in certain specified circumstances. Either party may terminate the Celest Agreement if the other party fails to cure its material breach of the Celest Agreement within a specified cure period, or immediately if the other party becomes bankrupt or insolvent.

Competition

We are aware of other companies that are developing technologies that may compete with elements of our gene circuit platform technologies, including A2 Biotherapeutics, Inc., Arsenal Biosciences, Inc., Beam Therapeutics Inc., CRISPR Therapeutics AG, Encoded Therapeutics, Inc., ImmPACT Bio USA, Inc., Intellia Therapeutics, Inc., MeiraGTx Holdings plc, Obsidian Therapeutics, Inc. and Strand Therapeutics Inc. We are also aware of other companies that are focused on the application of engineered CAR-based immune cell therapies, including NK cells, to oncology, and such competitors include Allogene Therapeutics, Inc., Artiva Biotherapeutics, Inc., Atara Biotherapeutics, Inc., Bristol-Myers Squibb Company, Century Therapeutics, Inc., Caribou Biosciences, Inc., Cytovia Therapeutics, Inc., Fate Therapeutics, Inc., Gilead Sciences, Inc., Lyell Immunopharma, Inc., Nkarta, Inc., Sana Biotechnology, Inc., Shoreline Biosciences, Inc., Takeda Pharmaceutical Company and Vor Biopharma Inc. Some of these companies may have substantially greater financial and other resources than we have, such as larger research and development staff and well-established marketing and salesforces. Mergers and acquisitions in the biotechnology industry may result in even greater resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, either alone or through collaborative arrangements with large and established companies.

These companies compete with us in recruiting scientific and managerial talent. Our success will partially depend on our ability to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates. Our competitors may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. 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.

Intellectual Property

Intellectual property is critical to our differentiated technology. Our overall strategy is to own and control all intellectual property related to our gene circuits. We protect our proprietary technology and intellectual property rights through a combination of wholly-owned patent rights, licensed patent rights in particular fields of use, trademark rights, trade secrets and know-how, contractual provisions and confidentiality procedures. Our general strategy includes protecting our proprietary technology and intellectual property rights domestically and in certain key foreign markets. We continually grow and supplement our intellectual property portfolio with new filings and

applications not only to strengthen the protection of proprietary technology and intellectual property rights, but also to protect and support the development and commercialization of current and future product candidates. In addition, we seek to protect our technological innovations and branding efforts by filing new patent and trademark applications at the appropriate time and in strategically relevant jurisdictions.

Our patent portfolio relates to our ongoing research and development activities and includes a combination of patents and pending patent applications licensed from third parties, pending patent applications jointly owned with third parties, and patent applications solely owned by us. The patents and pending patent applications in our portfolio can be categorized as relating to our gene circuit platform technologies, including Logic Gating gene circuits, Multi-Arming gene circuits, Regulator Dial gene circuits and Smart Sensor gene circuits; our product candidates, including SENTI-202 and SENTI-301A, as well as other possible pipeline product candidates; and alternative technologies, and our patents and patent application include claims directed to compositions, methods (including preparation, use, or treatment), processes, dosing and formulations. As of February 16, 2024, our in-licensed and owned patent portfolio consists of over 11 issued patents and 234 pending patent applications, of which we own or co-own 5 patents and 212 pending patent applications, and have licensed 6 patents and 22 pending patent applications.

The term of a patent in our patent portfolio varies depending upon a number of factors such as the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for 20 years from the earliest non-provisional filing date of the patent application to which the patent claims priority. In the United States, a term of a patent may be lengthened by patent term adjustment (PTA), which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In addition, in certain instances, the patent term of a U.S. patent that covers an FDA-approved drug may also be eligible for extension to recapture a portion of the term effectively lost as a result of clinical trials and the FDA regulatory review period, such extension is referred to as patent term extension (PTE). The restoration period cannot be longer than five years, and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. However there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. 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 non-provisional filing date of the patent application to which the patent claims priority. 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.

We also utilize trademark rights to protect our brand and have filed trademark applications for the marks “SENTI,” “SENTI BIOSCIENCES,” “SENTI BIO,” and Senti’s “S” logo in the United States and in certain marks in foreign countries. As of February 16, 2024, we own two United States trademark registrations, four pending and/or allowed United States trademark applications, and five foreign trademark registrations. We have also registered multiple internet domain names to further supplement the protection of our brand.

Government Regulation

The U.S. Food and Drug Administration, or 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, sampling post-approval monitoring and post-approval reporting of biologics such as those we are developing. Any product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local and foreign statutes and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements, or GLP;
- submission to the FDA of an investigational new drug application, or 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 according to the FDA's regulations commonly referred to as good clinical practice, or GCP, regulations and any additional requirements for the protection of human research subjects and their health information 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, if applicable, to assess compliance with the FDA's current Good Tissue Practice, or cGTP, requirements for the use of human cellular and tissue products, and of selected clinical investigation sites to assess compliance with GCPs;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

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 to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. Some preclinical testing may continue even after the IND is submitted. 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 before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial 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. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- 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, dose tolerance 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. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

In March 2022, the FDA released final guidance titled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce development costs and time.

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 in the intended therapeutic indication, particularly for long-term safety follow-up. Completion of 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 requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the safety, purity and potency 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 independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted 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. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once a BLA has been accepted for filing, the FDA’s goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product’s continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not

bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. For a product candidate that is also a human cellular or tissue product, the FDA also will not approve the application if the manufacturer is not in compliance with cGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates 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, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL 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 CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, 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 a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

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

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, new 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. Fast track designation applies to the combination of the product and the specific indication for which it is

being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product 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, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a biologic or indication approved under accelerated approval if, for example, the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by FDA, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to FDA for review during the pre-approval period.

The FDA established a new regenerative medicine advanced therapy, or RMAT, designation, which is intended to facilitate an efficient development program for, and expedite review of, any 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. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of such therapy.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation, do not change the standards for approval but may expedite the development or approval process. Even if a product candidate 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 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 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. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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 user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for a particular drug or biologic 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 indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, 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 a 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

Biologics 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 other entities involved in the manufacture and distribution of approved biological products, and those supplying products, ingredients, and

components of them, 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 requirements and other laws, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Changes to the manufacturing process or facility 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 also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

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. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent

decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Physicians may prescribe, in their independent professional and medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or 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. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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 regulatory exclusivity periods for all formulations, dosage forms, and indications of the active moiety. 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, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Coverage and Reimbursement

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

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

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. 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 existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no

assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act (the “ACA”) was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. Among the provisions of the ACA, of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and a cap on the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- extension of manufacturers’ Medicaid rebate liability under the Medicaid Drug Rebate Program; and
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% 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.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted.

- The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug 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.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, 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 and state 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. The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from \$7,050 to \$2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In addition, in February 2023, HHS issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

There has also been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing, which could negatively affect our business, financial conditions, results of operation and prospects.

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 current or future product candidates or additional pricing pressures.

Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our products. It is not clear how other future potential changes to the ACA will change the reimbursement model and market outlook for our current and future product candidates.

Other U.S. Healthcare Laws

Healthcare providers, physicians and third-party payors, among others, will play a primary role in the prescription and recommendation of any product candidates for which we obtain marketing approval. Our arrangements with third-party payors, providers and customers, among others, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations in the future that may constrain the business or financial

arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations in the United States and other countries, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, a person or entity from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order, arranging for or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare or 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. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs;
- federal civil and criminal false claims laws, including the federal False Claims Act, which provides for civil whistleblower or qui tam actions, and civil monetary penalties laws, that impose penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a referral made in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; Manufacturers can be held liable under the federal False Claims Act 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 federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and its implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses as well as their business associates and their subcontractors that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state, and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the Affordable Care Act, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the CMS information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests of physicians and their immediate family members; and
- analogous local, state and foreign laws and regulations, such as state anti-kickback and false claims laws that may apply to healthcare items or services reimbursed by third party payors, including private insurers, local, state and foreign transparency laws that require manufacturers to report information related to payments and transfers of value to other healthcare providers and healthcare entities, marketing expenditures, or drug pricing, state laws that require pharmaceutical companies to register certain employees engaged in marketing activities in the location and comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

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

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. In April 2014, the European Union adopted a Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The Clinical Trials Regulation is directly applicable in all Member States (and so does not require national implementing legislation in each Member State), and aims at simplifying and streamlining the approval of clinical studies in the European Union. For example, a single application is now made through the Clinical Trials Information System, for clinical trial authorization in up to 30 European Economic Area (“EEA”) (comprised of the EU Member States plus Norway, Iceland and Liechtenstein) countries at the same time and with a single set of documentation.

To obtain regulatory approval of a medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union. In the European Union, medicinal products can only be commercialized after obtaining a marketing authorization. There are two types of marketing authorization:

- The centralized marketing authorization is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”), and is valid throughout the entire territory of the EU. The centralized

procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the European Union, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a marketing authorization application under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National marketing authorizations, which are issued by the competent authorities of the Member States of the European Union and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this national marketing authorization can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national marketing authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Under the above described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the European Union make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities or innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a biosimilar or generic marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a biosimilar or generic marketing authorization can be submitted, and the innovator's data may be referenced, but no biosimilar or generic product can be marketed in the EU until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Even if a product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, the European Commission grants an orphan designation in respect of a product if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European

Union to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity during which no marketing authorization may be granted in the EU for a “similar medicinal product” to the authorized orphan product for the same therapeutic indication (subject to limited exceptions outlined below). A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies submitted in compliance with an EMA-approved pediatric investigation plan. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication as an authorized orphan product at any time if:

- The second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior;
- The marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or
- The marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product.

The aforementioned European Union rules are generally applicable in the EEA.

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission’s legislative proposals are approved (with or without amendment), they will be adopted into European Union law.

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

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

European Data Collection

The collection and processing of personal data (including health data) in the European Economic Area, or EEA and the United Kingdom, or UK is governed by the EU General Data Protection Regulation, or EU GDPR (with regards to the EEA) and the UK General Data Protection Regulation, or UK GDPR (with respect to the UK), as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018). The EU and UK data protection regimes are independent of each other but remain largely

aligned. However, the UK Government has introduced a Data Protection and Digital Information Bill, or Data Reform Bill into the UK legislative process to reform the UK data protection legal framework.

In this Form 10-K, “GDPR” refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR applies to any company established in the EEA/UK and to companies established outside the EEA/UK that process personal data in connection with the offering of goods or services to data subjects in the EEA/UK or the monitoring of the behavior of data subjects in the EEA/UK. The GDPR imposes numerous stringent requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of data subjects, providing detailed information to data subjects about how personal data is used, conducting privacy impact assessments for “high risk” processing, implementing safeguards to protect the security and confidentiality of personal data, implementing limitations on the retention of personal data, providing mandatory data breach notification, implementing “privacy by design” requirements, and taking certain measures when engaging service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside of the EEA/UK that do not ensure an adequate level of protection, including the United States in certain circumstances, unless derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses, or SCCs, and the UK International Data Transfer Agreement/Addendum, or UK IDTA) have been put in place. Where relying on the SCCs/UK IDTA for data transfers, transfer impact assessments are required to assess whether the recipient is subject to local laws which allow public authority access to personal data. Although the UK is regarded as a third country under the European Union’s GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and the UK government has issued a similar decision, therefore, transfers of personal data between the EU to the UK remain unrestricted.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States and the UK may result in fines up to €20 million (17.5 million for the UK GDPR) or 4% of a company’s global annual revenues for the preceding financial year, whichever is higher. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

Employees and Human Capital Resources

As of March 13, 2024, we had 48 employees, all of whom were full-time, consisting of clinical, research, operations, regulatory, finance and business development personnel. 13 of our employees hold Ph.D. or M.D. degrees. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. Of our executive officers, sixty-seven percent (67%) are people of color and sixty-seven percent (67%) are women. With respect to our employees overall, approximately seventy-seven percent (77%) are people of color and approximately forty-six percent (46%) are women.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

We currently occupy approximately 40,000 square feet of office and research and development space in South San Francisco, CA under a lease that expires in April, 2027, with an option to extend for an additional eight years. We also subleased our 92,000 square feet of manufacturing space under a sublease agreement to GeneFab that was executed in August 2023. We believe that this space, collectively, is sufficient to meet our existing needs.

Periodic Reporting and Financial Information

We are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company if (1) the market value

of our common stock held by non-affiliates is less than \$250 million as of the last business day of the second fiscal quarter, or (2) our annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter are less than \$100 million and the market value of our common stock held by non-affiliates is less than \$700 million as of the last business day of the second fiscal quarter.

Corporate Information

We were incorporated under the laws of the State of Delaware on June 9, 2016. Our principal executive office is located at 2 Corporate Drive, First Floor, South San Francisco, California 94080, and our telephone number is (650) 382-3281. Our website address is www.sentibio.com. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information on the website is not part of this document.

On June 8, 2022, Dynamics Special Purpose Corp., a Delaware corporation, or DYNS, consummated a previously announced Merger pursuant to the terms of the Business Combination Agreement with Senti Sub I, Inc., formerly Senti Biosciences, Inc., and Explore Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of DYNS, or Merger Sub. Pursuant to the terms of the Business Combination Agreement, Merger Sub merged with and into Senti Sub I, Inc., with Senti Sub I, Inc. surviving the merger as a wholly-owned subsidiary of DYNS. The Merger was approved by DYNS's stockholders at a meeting held on June 7, 2022. In connection with the consummation of the Merger on the Closing Date, DYNS changed its name from DYNS to Senti Biosciences, Inc. On June 9, 2022, our common stock, formerly of DYNS, began trading on the Nasdaq Global Market under the trading symbol "SNTI."

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge on our website located at www.sentibio.com as soon as reasonably practicable after they are filed with or furnished to the Securities and Exchange Commission, or the SEC. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC. The SEC's Internet website address is www.sec.gov.

A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of our Board of Directors are posted on our website, www.sentibio.com, under "Investors".

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before you decide to invest in common stock, you should consider carefully the risks described below, together with the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes appearing in this Annual Report. We believe the risks described below are the risks that are material to us as of the date of this Annual Report. Factors that could cause our actual results to differ materially from those in this Annual Report are any of the risks described in this Item 1A below. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. If any of the following risks actually occur, our business, results of operations and financial condition would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose part or all of your investment.

Summary Risk Factors

The risk factors set forth below represent a summary of some of the principal risk factors which potential investors in our securities should be aware of. Although each of these risks is important, this list is not and is not intended to be a substitute for investors reviewing all of the information in this Annual Report, including all risk factors which follow this summary.

- We are an early stage clinical biotechnology company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- Members of our management team have limited experience in managing the day-to-day operations of a public company and, as a result, we may incur additional expenses associated with the management of our company.
- Our history of recurring losses and anticipated expenditures raises substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.
- We may not achieve the intended objectives of our strategic prioritization plans announced in January 2023 and January 2024.
- We received clearance of our Investigational New Drug application, or IND, for our first product candidate, SENTI-202, in December 2023, under our collaboration with Celest Therapeutics for the clinical development of our SENTI-301A program, we anticipate that Celest Therapeutics will begin dosing patients with a product candidate for our SENTI-301A program in the second quarter of 2024, and the rest of our current product candidates are in preclinical development and our product candidates have never been tested in humans. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their ability to receive regulatory approval or to attain commercial viability.
- There can be no assurance that we will achieve all of the anticipated benefits of the transaction with GeneFab LLC and we could face unanticipated challenges.
- If any of our current or potential future product candidates is ever tested in humans, it may not demonstrate the safety, purity and potency, or efficacy, necessary to become approvable or commercially viable.
- Our gene circuit platform technologies are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.
- We may not be successful in our efforts to use and expand our gene circuit platform to expand our pipeline of product candidates.
- The market, physicians, patients, regulators and potential investors may not be receptive to our current or potential future product candidates and may be skeptical of the viability and benefits of our gene circuit pipeline technology because it is based on a relatively novel and complex technology.
- The occurrence of serious complications or side effects in connection with use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates or, post-approval, revocation of marketing authorizations or refusal to approve applications for new indications, which could severely harm our business, prospects, operating results and financial condition.

- We and our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the time frames that we or they announce or otherwise anticipate, which could have an adverse impact on our ability to receive payments under our collaboration agreements, harm our business and cause our stock price to decline.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for our current or future product candidates that we may develop.
- We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.
- We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily.
- Supply of our product candidates for preclinical and clinical development may become limited or interrupted or may not be of satisfactory quantity or quality, and we could experience delays relying on third-party manufacturers.
- We are exposed to a number of risks related to our supply chain for the materials required to manufacture our product candidates.
- We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, or if their platform technologies or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.
- Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material adverse effect on our business, financial condition, results of operations and prospects.
- Our business, operations and clinical development plans and timelines could be adversely affected by the impact of global economic and political developments, including high inflation and capital market disruption, the war in Ukraine, the current armed conflict in Israel and the Gaza Strip, economic sanctions and economic slowdowns or recession, including any lingering impact from the COVID-19 pandemic, or by the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we may conduct business, including our anticipated contract manufacturers, contract research organizations (“CROs”), shippers and others.

Risks Related to Our Limited Operating History and Financial Condition

We are an early stage clinical biotechnology company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are an early clinical stage biotechnology company with a history of losses. Since our inception, we have devoted substantially all of our resources to research and development, preclinical studies, building our management team and building our intellectual property portfolio, and we have incurred significant operating losses. Our net losses were \$71.1 million and \$58.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$244.3 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. To date, we have not generated any revenue from product sales, and we have not sought or obtained regulatory approval for any product candidate. Furthermore, we do not expect to

generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies, clinical trials, manufacturing and the regulatory approval process for our current and potential future product candidates.

We expect our net losses to increase substantially as we:

- continue to advance our gene circuit platform technologies;
- commence clinical trials of our current and future product candidates;
- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- acquire and in-license technologies aligned with our gene circuit platform technologies;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, and commercialization efforts;
- continue to develop, maintain, expand, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

However, the amount of our future losses is uncertain. Our ability to achieve or sustain profitability, if ever, will depend on, among other things, successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, ensuring our product candidates are manufactured on commercially reasonable terms, entering into potential future alliances, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we, or our existing or potential future collaborators, are unable to commercialize one or more of our product candidates, or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve or sustain profitability, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We will need substantial additional funding. If we are unable to raise capital when needed on acceptable terms, or at all, we may be forced to restructure our business or delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations.

We will need substantial additional funds to advance development of product candidates and our gene circuit platform, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future product candidates and technologies.

The development of biotechnology product candidates is capital-intensive. If any of our current or potential future product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, marketing and sales capabilities. We have used substantial funds to develop our gene circuit platform, SENTI-202, SENTI-301A, and other potential product candidates, and we will require significant funds to continue to develop our platform and conduct further research and development, including preclinical studies and clinical trials. In addition, we expect to incur significant additional costs associated with operating as a public company.

As of December 31, 2023, we had \$35.9 million in cash, cash equivalents, and short-term investments. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of platform technologies and product candidates are highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future capital requirements and the timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development of our current and potential future product candidates;
- the timing and progress of our development of our gene circuit platforms;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the terms of any current third-party manufacturing contract or biomanufacturing partnership or future manufacturing contract or biomanufacturing partnership we may enter into;
- our ability to maintain our current licenses and collaborations, conduct our research and development programs and establish new strategic partnerships and collaborations;
- the progress of the development efforts of our existing strategic partners and third parties with whom we may in the future enter into collaboration and research and development agreements;
- the costs involved in obtaining, maintaining, enforcing and defending patents and other intellectual property rights;
- supply chain disruptions, global political and market conditions, and inflationary pressures on our business;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and to hire and retain personnel, including personnel to support development of our product candidates and to satisfy our obligations as a public company.

To date, we have primarily financed our operations through the sale of equity securities and the sale of assets related to our manufacturing operations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, grants and other marketing and distribution arrangements. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms acceptable to us, if at all. If we are unable to obtain adequate financing when needed, our business, financial condition and results of operations will be harmed, and we may need to significantly modify our operational plans, or else we may not be able to continue as a going concern beyond twelve months from the issuance date of this Form 10-K. For example, in January 2023 we announced a strategic plan to focus internal resources on SENTI-202 and SENTI-401, to develop gene circuits for other programs with potential partners, and to suspend research and development efforts for SENTI-301A. In August 2023, we announced a transaction with GeneFab pursuant to which we transferred our in-house manufacturing operations and assets to GeneFab. In January

2024, we announced a strategic plan to focus our resource allocation to investment on clinical development of SENTI-202 and on partnership of our SENTI-301A program in China. In the future, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs, or commercialization efforts. Further, if we are unable to continue as a going concern, we might have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. Because of the numerous risks and uncertainties associated with the development and commercialization of our current and potential future product candidates and the extent to which we may enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials, including related manufacturing costs.

To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our current and potential future product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Moreover, the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline.

We do not expect to realize revenue from product sales or royalties from licensed products for the foreseeable future, if at all, and unless and until our current and potential future product candidates are clinically tested, approved for commercialization and successfully marketed.

Our streamlining of business operations, including workforce reduction and re-prioritization plan announced in January 2024, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In January 2024, we announced a reduction in workforce by approximately 37% in connection with streamlining our business operations to enable increased focus on SENTI-202 and to continue SENTI-301A program clinical development through a partnership in China. We have incurred certain one-time estimated severance and related costs as part of this resource allocation effort. We also cannot guarantee that we will not have to undertake additional workforce reductions or re-prioritization activities in the future. Further, we may not be able to enter into partnerships for programs that we do not intend to develop internally on acceptable terms or within the timeframes that we expect, or we may not realize the anticipated benefits of those partnerships we do secure, and we may be forced to dedicate additional time and resources to the maintenance of these programs or to our efforts to enter new or additional partnerships. Furthermore, our strategic streamlined business plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. In addition, if there are unforeseen expenses associated with such realignments in our business strategies, and we incur unanticipated charges or liabilities, then we may not be able to effectively realize the expected cost savings or other benefits of such actions which could have an adverse effect on our business, operating results and financial condition. If employees who were not affected by the workforce reduction seek alternate employment, this could result in us seeking contract support resulting in unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

We identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of shares of our common stock.

As previously reported, in connection with our preparation and the audit of our consolidated financial statements as of and for the year ended December 31, 2022, we and our independent registered public accounting firm identified a material weakness, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. The material weakness related to a lack of sufficient and adequate resources in the finance and accounting function that resulted in 1. lack of formalized risk assessment process, 2. lack of segregation of duties, and 3. ineffective process level control activities over (a) management review of journal entries, (b) account reconciliations and (c) non-routine, unusual or complex transactions.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

We implemented a risk assessment process and measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weakness, including hiring additional accounting personnel. However, the process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. Moreover, the rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and remediation. To maintain and improve the effectiveness of our financial reporting, we will need to commit significant resources, implement and strengthen existing disclosure processes controls, reporting systems, and procedures, train personnel and provide additional management oversight, all of which may divert attention away from other matters that are important to our business.

We cannot be certain that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, an independent registered public accounting firm has not yet performed an evaluation of our internal control over financial reporting, though such an evaluation will be required when we lose our status as an “emerging growth company” and become an “accelerated filer” or a “large accelerated filer.” When an evaluation by an independent registered public accounting firm is performed, such firm may issue a report that is qualified if it is not satisfied with our controls or the level at which our controls are documented, designed, operated, or reviewed.

Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. A material weakness in internal controls could result in our failure to detect a material misstatement of our annual or quarterly consolidated financial statements or disclosures. We may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. If we are unable to conclude that we have effective internal controls over financial reporting, investors could lose confidence in our reported financial information, which could have a material adverse effect on the trading price of the shares of our common stock.

We cannot be certain as to the timing of completion of our evaluation, testing and any remediation actions or the impact of the same on our operations. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. If we are not able to implement the requirements of Section 404 in a timely manner or with

adequate compliance, our independent registered public accounting firm when required may issue an adverse opinion due to ineffective internal controls over financial reporting, and we may be subject to sanctions or investigation by regulatory authorities, such as the SEC. As a result, there could be a negative reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. In addition, we may be required to incur costs in improving our internal control system and the hiring of additional personnel. Any such action could negatively affect our results of operations and cash flows.

Members of our management team have limited experience in managing the day-to-day operations of a public company and, as a result, we may incur additional expenses associated with the management of our company.

Members of our management team have limited experience in managing the day-to-day operations of a public company. As a result, we may need to obtain outside assistance from legal, accounting, investor relations, or other professionals that could be more costly than planned. These compliance costs will make some activities significantly more time-consuming and costly. If we lack cash resources to cover these costs in the future, our failure to comply with reporting requirements and other provisions of securities laws could negatively affect our stock price and adversely affect our potential results of operations, cash flow and financial condition.

Our ability to use net operating loss carryforwards (“NOLs”) and credits to offset future taxable income may be subject to certain limitations.

Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for 20 taxable years under applicable U.S. federal income tax law. Under current U.S. federal income tax law, NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2023, we had NOLs for U.S. federal and state income tax purposes of approximately \$136.0 million and \$71.6 million, respectively, a portion of which expire beginning in 2036 if not utilized. NOLs for U.S. federal tax reporting purposes of approximately \$132.5 million have an indefinite life.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an “ownership change” (defined under Section 382 of the Code and applicable Treasury Regulations as a greater than 50 percentage point change (by value) in a corporation’s equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have not determined whether our NOLs are limited under Section 382 of the Code. We may have experienced ownership changes in the past and may experience ownership changes in the future, including as a result of the Merger or subsequent shifts in our stock ownership (some of which are outside our control). Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheets, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

Changes in tax law may adversely affect us or our investors.

The U.S. rules dealing with federal, state, and local taxation are constantly under review by those involved in the legislative process, as well as by the U.S. Treasury Department. Changes to tax laws, which may have retroactive application, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and change are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial conditions, or results of operations. The existence, timing, and content of new tax laws are unpredictable, and could cause an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes

in tax law. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

The sale or issuance of our common stock to GeneFab may cause significant dilution and the sale of the shares of common stock acquired by GeneFab, or the perception that such sales may occur, could cause the price of our common stock to fall.

Pursuant to an option under the transaction with GeneFab, GeneFab may choose to invest up to approximately \$20 million to purchase up to 19,633,444 shares of our common stock, subject to certain limitations, including stockholder approval in certain circumstances and compliance with applicable law. The option becomes exercisable by GeneFab upon the execution of the license agreement, no later than August 7, 2026. The exercise of the option by GeneFab could result in a significant increase in the number of outstanding shares of our common stock and substantially dilute the ownership interest of our existing stockholders. In addition, we have agreed to register for resale these shares purchased by GeneFab under their option, subject to certain restrictions. If GeneFab chooses to sell its shares in the Company, the price of our shares could fluctuate based on the market price of the common stock during the period in which such sales occur. Additionally, the sale of a substantial number of shares of our common stock, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

It is not possible to predict the number of shares of our common stock, if any, that we may sell to Chardan Capital Markets LLC, or Chardan, under our common stock Purchase Agreement, or the Purchase Agreement, with Chardan, or the actual gross proceeds resulting from those sales, or the dilution to our stockholders from those sales.

On August 31, 2022, we entered into the Purchase Agreement with Chardan, pursuant to which Chardan may purchase from us up to \$50.0 million in shares of our common stock (the “Total Commitment”), upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement. To date, we have sold \$1.2 million in shares of our common stock to Chardan. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Chardan at our discretion from time to time until the earliest to occur of (i) October 1, 2025, (ii) the date on which Chardan has purchased the Total Commitment pursuant to the Purchase Agreement, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any successor market, and (iv) the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person or entity commences a proceeding against us, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

We generally have the right to control the timing and amount of any sales of our common stock to Chardan under the Purchase Agreement. Sales of our common stock to Chardan under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Chardan all or some of the common stock that may be available for us to sell to Chardan pursuant to the Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell all of the Total Commitment or how much in proceeds we may obtain under the Purchase Agreement. If we cannot sell securities under the Purchase Agreement, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could have a material adverse effect on our liquidity and cash position.

Because the purchase price per share of common stock to be paid by Chardan for the common stock that we may elect to sell to Chardan under the Purchase Agreement will fluctuate based on the market prices of our common stock at the time we elect to sell shares to Chardan pursuant to the Purchase Agreement it is not possible for us to predict, as of the date of this Annual Report on Form 10-K and prior to any such sales, the number of shares of common stock that we will sell to Chardan under the Purchase Agreement, the purchase price per share that Chardan will pay for shares of common stock purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Chardan under the Purchase Agreement.

The actual number of shares of our common stock issuable will vary depending on the then current market price of shares of our common stock sold to Chardan and the number of shares of common stock we ultimately elect to sell to Chardan under the Purchase Agreement. If it becomes necessary for us to issue and sell to Chardan under the

Purchase Agreement more than the 8,727,049 shares of common stock we registered pursuant to the Purchase Agreement, in order to receive aggregate gross proceeds equal to \$50.0 million under the Purchase Agreement, we will have to file with the SEC one or more additional registration statements to register under the Securities Act the resale by Chardan of any such additional shares of common stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our common stock under the Purchase Agreement. Under applicable Nasdaq rules, in no event may we issue to Chardan more than 19.99% of the total number of shares of common stock that were outstanding immediately prior to the execution of the Purchase Agreement, unless we obtain prior stockholder approval or if such approval is not required in accordance with the applicable Nasdaq rules. In addition, Chardan is not obligated to buy any common stock under the Purchase Agreement if such shares, when aggregated with all other shares of our common stock then beneficially owned by Chardan and its affiliates (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder), would result in Chardan beneficially owning common stock in excess of 4.99% of our outstanding shares of common stock. Our inability to access a portion or the full amount available under the Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business or results of operation.

Investors who buy common stock from Chardan at different times will likely pay different prices.

Pursuant to the Purchase Agreement, the timing, price and number of shares sold to Chardan will vary depending on when we choose to sell shares, if any, to Chardan. If and when we elect to sell any additional common stock to Chardan pursuant to the Purchase Agreement, after Chardan has acquired such common stock, Chardan may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices. As a result, investors who purchase shares from Chardan at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Chardan as a result of future sales made by us to Chardan at prices lower than the prices such investors paid for their shares from Chardan.

The sale or issuance of shares of our common stock to Chardan will result in additional outstanding shares and the resale of shares of our common stock by Chardan that it acquires pursuant to the Purchase Agreement, or the perception that such sales may occur, could cause the price of shares of our common stock to decrease.

As of the date of this Form 10-K, we have issued 1,400,000 shares of common stock to Chardan under the Purchase Agreement, including 100,000 shares issued to Chardan as consideration for its execution and delivery of the Purchase Agreement. The shares of common stock issuable under the Purchase Agreement may be sold by us to Chardan at our sole discretion, subject to the satisfaction of certain conditions in the Purchase Agreement, from time to time, until the earliest to occur of (i) October 1, 2025, (ii) the date on which Chardan has purchased the Total Commitment pursuant to the Purchase Agreement, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any successor market, and (iv) the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person or entity commences a proceeding against us, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors. The purchase price for shares of our common stock that we may sell to Chardan under the Purchase Agreement will fluctuate based on the trading price of shares of our common stock. Depending on market liquidity at the time, sales of shares of our common stock may cause the trading price of shares of our common stock to decrease. We generally have the right to control the timing and amount of any future sales of shares of our common stock to Chardan. Additional sales of shares of our common stock, if any, to Chardan will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Chardan all or some of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares of our common stock to Chardan, after Chardan has acquired shares of our common stock, Chardan may resell all, some or none of such shares of common stock at any time or from time to time in its discretion. Therefore, sales to Chardan by us could result in substantial dilution to the interests of other holders of shares of our common stock. In addition, if we sell a substantial number of shares of our common stock to Chardan under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares of our common stock or the mere existence of our arrangement with Chardan may make it more difficult for us to sell

equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

We may use our cash resources, including proceeds from sales of our common stock made pursuant to the Purchase Agreement, in ways with which you may not agree or in ways which may not yield a significant return.

We have broad discretion over the use of capital we have raised, including proceeds from sales of our common stock made pursuant to the Purchase Agreement, and you will not have the opportunity, as part of any decision to invest in our common stock, to assess whether the proceeds are being used appropriately. Accordingly, you will have to rely on the judgment of our management with respect to the use of these funds, with only limited information regarding management's specific intentions. We may spend all or a portion of the net proceeds of our prior financing activities, including sales of our common stock under the Purchase Agreement, in ways that are not what our stockholders may desire or that may not yield favorable results. Because of the number and variability of factors that will determine our use of the net proceeds, their ultimate use may vary substantially from their currently intended use. The failure by us to apply these funds effectively could harm our business, and the net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our common stock.

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

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. As of December 31, 2023, we had one letter of credit held with JPMorgan Chase Bank in the amount of approximately \$2.9 million and one letter of credit with Silicon Valley Bank, or SVB, in the amount of approximately \$0.5 million related to our facility leases. Due to the placement into receivership of SVB in March 2023, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to instruments or lending arrangements with such a financial institution, 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. In this regard, counterparties to credit agreements and arrangements with banks in receivership or other financial difficulty, and third parties (such as beneficiaries of letters of credit, among others), may experience direct impacts from the closure of or reorganization of such financial institution and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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. Although 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 certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, 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, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have or financial arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

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 decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws and otherwise have a material adverse impact on our business.

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

Our current product candidates are in early clinical or preclinical development and have never been tested in humans. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their commercial viability.

We have no products on the market or that have gained regulatory approval and we are just beginning the clinical development of our lead product candidate. None of our product candidates has ever been tested in humans. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing product candidates, either alone or with collaborators.

Before obtaining regulatory approval for the commercial distribution of our product candidates, we or a collaborator must conduct extensive preclinical studies, followed by clinical trials to demonstrate the safety, purity and potency, or efficacy of our product candidates in humans. There is no guarantee that the FDA will permit us to conduct clinical trials in accordance with our plans, or at all. Further, we cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, our clinical protocols or if the outcome of our preclinical studies will ultimately support the further development of our preclinical programs or testing in humans. As a result, we cannot be sure that we will be able to submit IND or similar applications for our proposed clinical programs on the timelines we expect, if at all, and we cannot be sure that our submission of additional INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials for our product candidates to begin.

Our current product candidates are in early clinical and preclinical development and we are subject to the risks of failure inherent in the development of product candidates based on novel approaches, targets and mechanisms of action. Although we received IND clearance for SENTI-202 from the FDA in December 2023 and we anticipate initiating a phase 1 clinical trials for SENTI-202 in the second quarter of 2024, there is no guarantee that we will be able to proceed with clinical development of SENTI-202 or any of our other product candidates or that any product candidate will demonstrate a clinical benefit once we advance these candidates to testing in patients. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by early clinical stage biotechnology companies such as ours.

We may not be able to access the financial resources to continue development of, or to enter into any collaborations for, any of our current or potential future product candidates. This may be exacerbated if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, a product candidate, such as:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon any or all of our programs;
- adverse events experienced by participants in our clinical trials or by individuals using therapeutics similar to our product candidates;
- delays in submitting INDs or comparable foreign applications, or delays or failures to obtain the necessary approvals from regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;

- conditions imposed by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- conditioning patients with fludarabine in advance of administering our product candidates, which may be difficult to source, costly, or increase the risk of infections and other adverse side effects;
- chemistry, manufacturing and control (“CMC”) challenges associated with manufacturing and scaling up biologic product candidates to ensure consistent quality, stability, purity and potency among different batches used in clinical trials;
- greater-than-anticipated clinical trial costs;
- poor potency or effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory authority inspection and review of a clinical trial or manufacturing site;
- delays as a result of a pandemic or other public health emergency, or events associated with a pandemic or other health emergency;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; or
- the FDA or other regulatory authorities interpreting our data differently than we do.

Further, we and any existing or potential future collaborator may never receive approval to market and commercialize any product candidate. Even if we or any existing or potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or potential future collaborator may also be subject to post-marketing testing requirements to maintain regulatory approval.

If any of our current or potential future product candidates is ever tested in humans, it may not demonstrate the safety, purity and potency, or efficacy, necessary to become approvable or commercially viable.

None of our current product candidates have ever been tested in humans. We may ultimately discover that our current product candidates do not possess certain properties that we believe are helpful for therapeutic effectiveness and safety or would otherwise support the submission of an IND on the timelines we expect, or at all. We do not know if the observations we have made regarding our gene circuits generally and our product candidates in particular will translate into any clinical response when tested in humans. As an example, while the TAA CD33 has been clinically validated as a target for an approved antibody-drug conjugate therapy, it has not been clinically

validated as a target for CAR-NK or CAR-T therapies, and may not prove to be a clinically sufficient target for the CAR-NK therapies we are developing. As a result of these uncertainties related to our gene circuit platform technologies and our product candidates, we may never succeed in developing a marketable product based on our current product candidates. If any of our current or potential future product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our gene circuit platform technologies are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

We are seeking to identify and develop a broad pipeline of product candidates using our gene circuit platform technologies. The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. We are not aware of any FDA approved therapeutics utilizing similar technologies as ours. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our platform technologies is preliminary. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have not tested any of our current product candidates in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and efficacy of our product candidates. In addition, our gene circuit technologies may have potential safety risks.

Given the novelty of our technologies, we intend to work closely with the FDA and comparable foreign regulatory authorities to evaluate our proposed approaches to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

The occurrence of serious complications or side effects in connection with the use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates, or, post-approval, revocation of marketing authorizations or refusal to approve applications for new indications, which could severely harm our business, prospects, operating results, and financial condition.

Undesirable side effects caused by any of our current or potential future product candidates could cause 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 regulatory authorities. While we have not yet initiated clinical trials for SENTI-202, or any other product candidate, it is likely that there will be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. For example, if the NOT GATE gene circuit, engineered into one of our product candidates, such as SENTI-202, does not provide a clinically sufficient level of inhibition, it may kill healthy cells that it has been designed to preserve or may cause systemic immune cytotoxicity. It is possible that safety events or concerns such as these or others could negatively affect the development of our product candidates, including adversely impacting patient enrollment among the patient populations that we intend to treat. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. To date, we have not observed any such effects in our preclinical studies, but there can be no guarantee that our current

or future product candidates will not cause such effects in clinical trials. Any of these occurrences may materially and adversely impact our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly large number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

In the event that any of our current or potential future product candidates receives regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following events could occur, which could result in the loss of significant revenue to us and materially and adversely impact our results of operations and business:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions, or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; 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 significantly harm our business, results of operations, and prospects.

We may not be successful in our efforts to use and expand our gene circuit platform to expand our pipeline of product candidates.

A key element of our strategy is to use and advance our gene circuit platform to design, test and build our portfolio of product candidates focused on allogeneic gene circuit-equipped CAR-NK cell therapies for the treatment of cancer. Although our research and development efforts to date have resulted in our discovery and preclinical development of SENTI-202, SENTI-301A, and other potential product candidates, we only received clearance of our IND for SENTI-202 in December 2023, and to date, we have not tested any of our product candidates in human. We cannot assure you that any of our existing product candidates will advance to clinical trials or, if they do, that such trials will demonstrate these product candidates to be safe or effective therapeutics, and we may not be able to successfully develop any product candidates. Even if we are successful in expanding our pipeline of product candidates, any additional product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future.

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a

number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Although a substantial amount of our efforts will focus on the planned clinical trials and potential approval of the current and potential future product candidates we are evaluating, an element of our long term strategy is to discover, develop, and globally commercialize additional targeted therapies beyond our current product candidates to treat various conditions and in a variety of therapeutic areas. Even if we identify investigational therapies that initially show promise, we may fail to successfully develop and commercialize such products for many reasons, including the following:

- the research methodology used may not be successful in identifying potential investigational therapies;
- competitors may develop alternatives that render our investigational therapies obsolete;
- investigational therapies we develop may be covered by third parties' patents or other exclusive rights;
- an investigational therapy may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio;
- an investigational therapy may not be capable of being produced in clinical or commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by patients, the medical community or third-party payors.

Identifying new investigational therapies requires substantial technical, financial and human resources, whether or not any investigational therapies are ultimately identified. Because we have limited financial and human resources, we may initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, if we do not accurately evaluate the commercial potential or target market for a particular product candidate or technology, we may relinquish valuable rights to that product candidate or technology through collaborations, 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 or technology.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

The market, physicians, patients, regulators and potential investors may not be receptive to our current or potential future product candidates and may be skeptical of the viability and benefits of our gene circuit pipeline technology because it is based on a relatively novel and complex technology.

The market, physicians, patients, regulators and potential investors, may be skeptical of the viability and benefits of our gene circuit pipeline technology or our product candidates because they are based on a relatively novel and complex technology and there can be no assurance that our product candidates or platform technologies will be understood, approved, or accepted. If potential investors are skeptical of the success of our pipeline products, our ability to raise capital and the value of our stock may be adversely affected. If physicians, patients, or regulators do not understand or accept our gene circuit platform technologies or our product candidates, we may be delayed in or unable to develop our product candidates.

Even if regulatory approval is obtained for a product candidate, including SENTI-202, we may not generate or sustain revenue from sales of approved products. Market acceptance of our gene circuit platform technologies and our current and potential future product candidates, if approved, will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates and gene circuit technologies in general;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the success of our physician education programs;
- the availability of coverage and adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material adverse impact on our business, financial condition, results of operations, and prospects.

While we believe our pipeline will yield multiple INDs, we may not be able to file additional INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We expect our pipeline to yield multiple INDs in addition to our IND for SENTI-202 that was cleared by the FDA in December 2023. We cannot be sure that submission of an IND will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. The manufacturing of our product candidates, including SENTI-202, remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and control related topics, including product specifications, will be a focus of IND reviews, which may delay the clearance of any future INDs we may submit. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or

clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees (“IBCs”), as set forth in the National Institutes of Health (“NIH”), Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

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

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, 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 interim, preliminary or topline results that we report may differ from future results of the same study or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Interim, topline or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of 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, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We and our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.

From time to time, we expect that we will make public statements regarding the expected timing of certain milestones and key events, such as the commencement and completion of preclinical and IND-enabling studies in our own internally-developed programs or in our product candidate discovery programs with collaborators, as well as the submission and clearance of INDs and the commencement and completion of planned clinical trials in those programs. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or any future collaborators' product candidate discovery and development programs, the amount of time, effort and resources committed by us and any future collaborators, the availability of resources for us and our collaborators to commence and conduct clinical development and manufacturing activities, and the numerous uncertainties inherent in the development of therapies. As a result, there can be no assurance that our or any future collaborators' programs will advance or be completed in the time frames we or they announce or expect. If we or any collaborators fail to achieve one or more of these milestones or other key events as planned, our business could be materially adversely affected, and the price of our common stock could decline.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our current and potential future product candidates are based on new technologies and discovery approaches, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, the FDA or other regulatory authorities may require us to perform additional testing before commencing clinical trials and be hesitant to allow us to enroll patients impacted with our targeted disease indications in our future clinical trials. If we are unable to enroll patients impacted by our targeted disease indications in our future clinical trials, we would be delayed in obtaining potential proof-of-concept data in humans, which could extend our development timelines. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates may be significant. Accordingly, our clinical trial costs are likely to be high and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may not be able to initiate or continue any clinical trials for our current or potential future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. We cannot predict how difficult it will be to enroll patients for trials in the indications we are studying. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity and availability of clinical trial sites for prospective patients;
- willingness of physicians to refer their patients to our clinical trials;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential risks and benefits of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient informed consents;
- patient eligibility and exclusion criteria for the trials;
- ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, such as potential pandemics that may limit the availability of patients, principal investigators or staff or clinical sites to participate in our clinical trials.

In addition, our future clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, 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. Additionally, because some of our clinical trials will be in patients with advanced disease who may experience disease progression or adverse events independent from our product candidates, such patients may be unevaluable for purposes of the trial and, as a result, we may require additional enrollment. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of these clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, including the endpoint measures required for regulatory approval and our statistical plan;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indications as our product candidates;
- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;

- delay or failure to manufacture sufficient quantities or inability to produce quantities of consistent quality, purity and potency of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse events experienced by patients, including possible deaths;
- lack of efficacy or failure to measure a statistically significant clinical benefit within the dose range with an acceptable safety margin during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the impact of, and delays related to, health epidemics such as the COVID-19 pandemic;
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and
- the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic collaborator that has responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for our current or future product candidates that we may develop.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. We may seek orphan drug designation for certain indications for our product candidates in the future. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Orphan drug designation can entitle a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

In addition, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. The FDA may reduce the seven-year exclusivity if the same drug from a competitor demonstrates clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, and while we may seek orphan drug designation for our product candidates, we may never receive such designations. In addition, the FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through

protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Risks Related to Our Reliance on Third Parties

There can be no assurance that we will achieve all of the anticipated benefits of the transaction with GeneFab and we could face unanticipated challenges.

We may not realize some or all of the anticipated benefits from the transaction with GeneFab and we may encounter post-closing risks. For example, the conditions for our receipt of the deferred consideration payable to us under the Framework Agreement, dated August 7, 2023, by and among us, GeneFab and Valere Bio, Inc. (“Valere”) may not be achieved on the timelines we anticipate, or at all, which could adversely affect our business, financial conditions, cash flow, and results of operations. In addition, the conditions for our receipt of proceeds under the Seller Economic Share Agreement, dated August 7, 2023, by and among us, GeneFab and Valere also may not be achieved. Furthermore, disagreements with GeneFab over these obligations could require or result in litigation or arbitration, which would be time-consuming and expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations.

Further, we may experience loss of institutional knowledge due to the transfer of a significant number of our employees to GeneFab, which could harm our business. Moreover, the transition to a new company may require significant time and resources from the employees of GeneFab, which may disrupt GeneFab’s business and distract its management from other responsibilities, which may then result in GeneFab’s failure to achieve anticipated manufacturing production, which could adversely affect our timelines for clinical trials of our product candidates to the extent they are manufactured by GeneFab and our financial and operating results.

We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily.

We expect to rely on third-party clinical investigators, CROs, testing laboratories, clinical data management organizations and consultants to design, conduct, supervise and monitor certain preclinical studies and any clinical trials. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of such preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs, testing laboratories, and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and contract manufacturing organizations and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

Despite our reliance on third parties, we will ultimately be responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, including good laboratory practice, or GLP, good clinical practice, or GCP, cGMP, and cGTP. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of

trial sponsors, principal investigators and trial sites. If we or any of our CROs, clinical sites and investigators fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency, or EMA, or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates FDA regulatory requirements as well as federal or state healthcare laws and regulations or healthcare privacy and security laws.

If third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We depend on strategic partnerships and collaboration arrangements, such as our collaboration arrangements with Spark Therapeutics, Inc., or Spark, BlueRock Therapeutics, Inc., or BlueRock, and Celest Therapeutics (Shanghai) Co. Ltd., or Celest, for the application of our gene circuit platform technology to the development and commercialization of potential product candidates in certain indications, and if these arrangements are unsuccessful, this could impair our ability to generate revenues and materially harm our results of operations.

Our business strategy for exploiting the potential of our gene circuit platform technology is dependent upon maintaining our current arrangements and establishing new arrangements with strategic partners, research collaborators and other third parties. We currently have collaboration agreements with Spark, BlueRock and Celest. These collaboration agreements provide for, as the case may be, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under these arrangements, our collaborators are typically responsible for, in the applicable territories and fields:

- electing to advance product candidates through preclinical and/or into clinical development;
- conducting clinical development and obtaining required regulatory approvals for product candidates; and
- commercializing any resulting products.

As a result, we may not be able to conduct these collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

Additionally, the development and commercialization of potential product candidates under our collaboration agreements could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our collaborators:

- shifts its priorities and resources away from our collaborations due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- ceases development in therapeutic areas which are the subject of our collaboration;

- fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product;
- changes the success criteria for a particular product candidate, thereby delaying or ceasing development of such product candidate;
- significantly delays the initiation or conduct of certain activities which could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product candidate that competes, either directly or indirectly, with our product candidates;
- does not obtain the requisite regulatory approval of a product candidate;
- does not successfully commercialize a product candidate;
- encounters regulatory, resource or quality issues and is unable to meet demand requirements;
- exercises its rights under the agreement to terminate the collaboration, or otherwise withdraws support for, or otherwise impairs development under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of research and development activities for such product candidate; and
- uses our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of our existing collaborations or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payment, sharing of profits, and other benefits under such agreement. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations. Furthermore, pursuant to certain of our agreements, we are required to engage certain parties unless the parties determine that a party is unable to provide such services. If we license or otherwise grant rights to certain products developed by us to a third party, we may need to impose this obligation on a third party acquirer or strategic partner.

We may not be able to enter into additional strategic transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize current and potential future product candidates and technologies, impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we consider strategic transactions, such as collaborations, regional partnerships for the co-development and/or co-commercialization of our product candidates in selected territories, acquisitions of companies, asset purchases, joint ventures, out- or in-licensing of product candidates or technologies and partnerships involving our gene circuit platform technology. For example, we will evaluate and, if strategically attractive, seek to enter into collaborations, including with biotechnology or biopharmaceutical companies, contract development manufacturing organizations or hospitals. On November 6, 2023, we announced that we had entered into a strategic collaboration with Celest for the clinical development of our SENTI-301A program to treat solid tumors in China. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. If we are not able to enter into strategic transactions, or if we fail to realize a benefit from the collaboration

with Celest or from a transaction with a different organization, we may not have access to required liquidity or expertise to further develop our potential future product candidates or our gene circuit platform. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business.

We also may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely, any new collaboration that we do enter into may be on terms that are not optimal for us, our product candidates or our technologies. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to negotiate and manage a collaboration or develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and technologies and have a negative impact on the competitiveness of any product candidate or technology that reaches market.

In addition, to the extent that any future collaborators terminate a collaboration agreement, we may be forced to independently develop our current and future product candidates and technologies, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandon product candidates and technologies altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Manufacturing

Manufacturing our current or future product candidates is complex and the third parties upon whom we rely to provide manufacturing services may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or, if approved, for commercial sale, for commercial purposes could be delayed or halted entirely.

The process of manufacturing our current or future product candidates is complex, difficult, variable, and highly regulated, and it requires significant expertise, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates is also extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminants are discovered in our product candidates or the manufacturing facilities in which they are made, the facilities may need to be closed for an extended period of time to investigate and remedy the contamination. As a result of the complexities, the cost to manufacture biologics in general, and our cell-based product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third party manufacturing organizations, or CMOs, and in particular GeneFab, for the manufacture of our current or future product candidates. Under our Development and Manufacturing Services Agreement with GeneFab, we are obligated to engage GeneFab for certain manufacturing services subject to GeneFab's meeting of certain criteria. GeneFab and any other CMO may not be able to provide adequate resources or capacity to meet our needs. If GeneFab or any other CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. This could significantly delay our clinical trials supply as we establish alternative supply sources and the shift to a different CMO could be expensive. In some cases, the technical skills required to manufacture our product candidates or products, if approved, may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts.

Supply of our product candidates for preclinical and clinical development may become limited or interrupted or may not be of satisfactory quantity or quality, and we may experience delays if GeneFab is unable to consistently and reliably manufacture any current and future products and we are required to rely on third-party back-up manufacturers.

Initial manufacturing efforts under our agreements with GeneFab will focus on our lead program, SENTI-202. GeneFab has never operated a cGMP facility before. GeneFab may not have the ability to consistently and reliably manufacture SENTI-202 in sufficient quality and quantity to support the planned clinical trials, which could negatively impact our overall development timelines. In addition, quality, reproducibility, stability, consistency issues may arise during manufacturing activities and may result in lower yields than initially expected. We do not currently have arrangements in place for a redundant or second-source supply in the event the facility we sublease to GeneFab is not operational or GeneFab is otherwise unable to meet our supply requirements for our preclinical studies and planned clinical trials. Any delays in manufacturing our product candidates could impede, delay, limit or

prevent our drug development efforts, which could harm our business, results of operations, financial condition and prospects.

We do not currently produce our product candidates in quantities sufficient for preclinical and clinical development. We cannot be sure that the manufacturing processes employed by GeneFab or the technologies incorporated for manufacturing will result in viable or scalable yields of our product candidates that will be safe, effective, and meet market demand. GeneFab and any other third-party manufacturers we may contract with must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP and cGTP. We have no control over the ability of GeneFab or other third-party manufacturers we may contract with to maintain adequate control, quality assurance and qualified personnel required to meet our preclinical and clinical needs, if any. In the event that we or any third-party manufacturer fails to comply with such requirements or to perform obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to or enter into an agreement with another third party, which we may not be able to do on reasonable terms, or at all. In some cases, the technical skills or technology required to manufacture our current and future product candidates may be difficult or impossible to transfer to a third party and a feasible alternative may not exist. If we are required to change manufacturing facilities or manufacturers for any reason, we will be required to verify that the new facilities and procedures comply with quality standards and with all applicable regulations and guidelines. We may also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturing facility could negatively affect our ability to develop product candidates in a timely manner or within budget.

Furthermore, we rely on third parties to manufacture our product candidates and critical raw materials. These third parties may have limited experience working with companies similar to us, may not perform satisfactorily, and may not be able to meet the preclinical and clinical development timeline, resulting in delays. Our reliance on third-party manufacturers exposes us to potential risks, such as the following:

- we may be unable to contract with or maintain existing relationships with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any product candidate that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our products;
- our third-party manufacturers might be unable to formulate and manufacture our product candidates and products in the volume and of the quality required to meet our clinical and commercial needs, if any; and
- our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials through completion or to successfully produce, store and distribute our commercial products, if approved.

Each of these risks could delay or have other adverse impacts on our clinical trials and the approval and commercialization of our product candidates, potentially resulting in higher costs, reduced revenues or both.

In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, and to regulatory applications, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer, and therefore delay timelines. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

If we receive regulatory approval for any product candidate and we are unable, for any reason, to have sufficient quantities of the product produced, or if we are unable to obtain or maintain third-party manufacturing arrangements on commercially reasonable terms, we may not be able to commercialize the product candidate successfully. Failure to execute on our manufacturing requirements and comply with cGMP and cGTP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;

- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of potential future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

GeneFab or any other third-party manufacturers that we use may be unable to successfully scale the manufacturing of our current or potential future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our current and potential future product candidates and commercializing approved products candidates, if any. GeneFab has never operated a cGMP facility before.

In order to conduct clinical trials for our current and potential future product candidates or to commercialize any approved product candidates, we will need to manufacture large quantities of these product candidates. We currently expect to rely exclusively on GeneFab to produce required quantities of SENTI-202. We, GeneFab, or any future manufacturing partners, may be unable to successfully scale-up the manufacturing process or to otherwise increase capacity for any current or potential future product candidate in a timely or cost-effective manner, or at all. In addition, quality, reproducibility, stability, consistency issues may arise during scale-up activities and may result in lower yields than initially expected. While we believe GeneFab will be able to sufficiently scale to produce quantities of SENTI-202 and future product candidates required to advance our preclinical studies and clinical trials, any significant revisions to the manufacturing process may create delays, which could negatively impact our overall development timelines.

We are exposed to a number of risks related to our supply chain for the materials required to manufacture our product candidates.

Manufacturing our product candidates is highly complex and requires sourcing specialty materials. Many of the risks associated with the complexity of manufacturing our final products are applicable to the manufacture and supply of the raw materials. In particular, these starting materials are subject to inconsistency in yields, variability in characteristics, contamination, difficulties in scaling the production process and defects. Similar minor deviations in the manufacturing process for these starting materials could result in supply disruption and reduced production yields for our final product. In addition, we rely on third parties for the supply of these materials exposing us to similar risks of reliance on third parties as described above with respect to the manufacturing and supply of our drug products.

Our manufacturing processes requires many reagents, some of which are drug substance intermediates used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could

be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As GeneFab continues to develop and scale the manufacturing process for our product candidates, we expect that there will be a need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. These rights may not be able to be obtained with respect to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned or future clinical trials conducted with the altered materials. We may also need to verify, such as through a manufacturing comparability study, that any changes to the manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Risks Related to Our Business and Operations

If the market opportunities for our current and potential future product candidates, including SENTI-202 and SENTI-301A, are smaller than we believe they are, our future product revenues may be adversely affected, and our business may suffer.

Our understanding of the number of people who suffer from diseases that our current product candidates may be able to treat are based on estimates. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for our candidates may further be reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from our product candidates.

Further, there are several factors that could contribute to making the actual number of patients who receive our current or potential future product candidates less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, or if their platform technologies or product candidates are more effective, have fewer side effects, or less expensive our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of cell and gene therapies is highly competitive. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, other biopharmaceutical companies and specialized biotechnology companies, as well as technology and/or therapeutics being developed at universities and other research institutions. Our competitors are often larger and better funded than we are. Our competitors have developed, are developing or will develop product candidates and processes competitive with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that are currently in development or that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. There is intense and rapidly evolving competition in the biotechnology and biopharmaceutical fields. We believe that while our gene circuit platform, its associated intellectual property portfolio, the characteristics of our current and potential future product candidates and our scientific and technical know-how together give us a competitive advantage in this space, competition from many sources remains.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our product candidates, the ease with which our product candidates can be administered, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products and product candidates could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products and product candidates may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such product. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of key executive management, advisors and other specialized personnel, including Timothy Lu, our Chief Executive Officer and President, Kanya Rajangam, our Head of Research and Development and Chief Medical Officer, and Deborah Knobelman, our Chief Financial Officer and Head of Corporate Development. Our senior management may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our employees. The loss of one or more members of our executive team, management team or other key employees or advisors could delay our research and development programs and have a material adverse effect on our business, financial condition, results of operations and prospects.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult 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 successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these 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. In addition, 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 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 pursue our growth strategy will be limited.

We may experience difficulties in managing our growth and expanding our operations.

We have limited experience in therapeutic development. As our current and potential future product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development and regulatory capabilities or contract with other organizations to provide these capabilities for us.

To execute on our anticipated operating plans, we will need to continue to implement and improve our managerial, operational, and financial systems, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively expand our operations, manage any expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems and procedures.

We may also experience difficulties in the discovery and development of potential future product candidates using our gene circuit platform if we are unable to meet demand as we grow our operations. In the future, we also expect to have to manage additional relationships with collaborators, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures and secure adequate facilities for our operational needs. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

If any of our product candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We currently have no sales, marketing or distribution capabilities or experience. We will need to develop internal sales, marketing and distribution capabilities to commercialize each current and potential future product candidate that gains, if ever, FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with third parties, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business and results of operations could be materially and adversely affected.

Our commercial relationships with entities outside of the United States and our potential future international operations may expose us to business, political, operational and financial risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our future clinical trials may be conducted outside of the United States and we may enter into key supply arrangements or do other business with persons outside of the United States. For example, in November 2023, we entered into a strategic collaboration with Celest, a China-based biotechnology company, for the clinical development of a product candidate for our SENTI-301A product to treat solid tumors in China. Furthermore, if we or any future collaborator succeeds in developing any products, we anticipate marketing them in the European Union and other jurisdictions in addition to the United States, including China. If approved, we or any future collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the United States, including China. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as those relating to privacy, data protection and cybersecurity, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the commercialization of our product candidates in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries, including China among other countries.

In addition, legislative proposals are pending that, if enacted, could negatively impact U.S. funding for certain biotechnology providers having relationships with foreign adversaries or which pose a threat to national security. The potential downstream adverse impacts on entities having only commercial relationships with any impacted biotechnology providers is unknown but may include supply chain disruptions or delays. Any of these factors could harm our ongoing international operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we conduct preclinical studies and future clinical trials of our current and potential future product candidates, we will be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of these product candidates. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we or any future collaborators may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators, consultants and commercial collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial collaborators. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and financial condition, including the imposition of significant criminal, civil and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

We depend on sophisticated information technology systems and data processing to operate our business. If we experience security or data privacy breaches, security incidents or compromises, or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

We rely on information technology systems and data processing that we or our service providers, collaborators, consultants, contractors or partners operate to collect, process, transmit and store electronic information in our day-

to-day operations, including a variety of personal data, such as name, mailing address, email addresses, phone number and potentially clinical trial information. Additionally, we, and our service providers, collaborators, consultants, contractors or partners, do or will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other information to host or otherwise process some of our anticipated future clinical data and that of users, develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes. Our internal computer systems and data processing and those of our third-party vendors, consultants, collaborators, contractors or partners, including future CROs may be vulnerable to a cyber-attack (including supply chain cyber-attacks), malicious intrusion, breakdown, destruction, loss of data privacy, actions or inactions by our employees or contractors that expose security vulnerabilities, theft or destruction of intellectual property or other confidential or proprietary information, business interruption or other significant security incidents or compromises. As the cyber-threat landscape evolves, these attacks are growing in frequency, level of persistence, sophistication and intensity, and are becoming increasingly difficult to detect. In addition to traditional computer “hackers,” threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), phishing and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). These risks may be increased as a result of pandemics, owing to an increase in personnel working remotely and higher reliance on internet technology. 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.

There can be no assurance that we, our service providers, collaborators, consultants, contractors or partners will be successful in efforts to detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, compromises, or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data. Any failure by us or our service providers, collaborators, consultants, contractors or partners to detect, prevent, respond to or mitigate security breaches, incidents, compromises, or improper access to, use of, or inappropriate disclosure of any of this information or other confidential or sensitive information, including patients’ personal data, or the perception that any such failure has occurred, could result in claims, litigation, regulatory investigations and other proceedings, significant liability under state, federal and international law, and other financial, legal or reputational harm to us. Further, such failures or perceived failures could result in liability and a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in our research, delays to commercialization of our product candidates, lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cashflow. For example, the loss or alteration of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Additionally, applicable laws and regulations relating to privacy, data protection or cybersecurity, external contractual commitments and internal privacy and security policies may require us to notify relevant stakeholders if there has been a security breach, including affected individuals, business partners and regulators. Such disclosures are costly, and the disclosures or any actual or alleged failure to comply with such requirements could lead to a materially adverse impact on the business, including negative publicity, a loss of confidence in our services or security measures by our business partners or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or other data protection obligations related to information security incidents, compromises, or security breaches.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research, development and manufacturing involve the use of hazardous materials and various chemicals. We maintain quantities of various flammable and toxic chemicals that are required for our research, development and manufacturing activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing,

handling and disposing of these materials comply with the relevant guidelines of the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Although we have some environmental liability insurance, we may not maintain adequate insurance for all environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our business, operations and clinical development plans and timelines could be adversely affected by global economic and political developments, including high inflation and capital market disruption, the war in Ukraine, the armed conflict in Israel and the Gaza Strip, economic sanctions and economic slowdowns or recessions, including any lingering impact from the COVID-19 pandemic, or the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we may conduct business, including our anticipated contract manufacturers, CROs, shippers and others.

Any global financial crisis or slowdown could cause volatility and disruptions in the capital and credit markets. Similarly, any global health epidemic, such as the COVID-19 pandemic, could cause disruptions in our operations and in the operations of third-party manufacturers, CROs, and other third-parties on whom we rely. More recently, the global economy has been impacted by increasing interest rates and high inflation, as well as by the war in Ukraine and the armed conflict in Israel and the Gaza Strip, and the possibility of a wider European and/or Middle-East or global conflict. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, or at all. Additionally, a weak or declining economy or international trade disputes could strain our suppliers, some of whom are located outside the United States, potentially resulting in supply disruption. Also, the global COVID-19 pandemic and government measures taken in response had a significant impact on businesses and commerce worldwide. In connection with COVID-19, we implemented work-from-home policies for most employees. In the event we are required to implement similar policies in connection with future global health emergencies, these policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of a health epidemic, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and future clinical trials may be affected by global health emergencies. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward addressing pandemic concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to illness during a global health emergency or experience additional restrictions by their institutions, city or state, our preclinical studies and future clinical trial operations could be adversely impacted.

The global COVID-19 pandemic disrupted healthcare delivery and healthcare regulatory systems. Such disruptions could divert healthcare resources, or delay the review and approval by the FDA or other regulatory bodies, thereby causing delay for our clinical trials. During a global health crisis, certain manufacturing facilities and materials may be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials, which could lead to delays in these trials. These and similar, and perhaps more severe, disruptions in our operations could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

The effects of a pandemic could have a material impact on our operations, and to the extent a pandemic adversely affects our business, results of operations, cash flows, financial condition and/or prospects, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Market volatility and economic downturns may harm our business and results of operations and negatively affect our stock price.

Our overall performance depends, in part, on worldwide economic conditions. In recent months, we have observed increased economic uncertainty in the United States and abroad. Impacts of such economic weakness include:

- declining overall demand for goods and services, leading to reduced profitability;
- reduced credit availability;
- higher borrowing costs;
- reduced liquidity;
- volatility in credit, equity and foreign exchange markets; and
- bankruptcies.

These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affect our business and our results of operations and negatively affect our stock price.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new solutions, retain or expand our current levels of personnel, improve our existing solutions, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing solutions;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing

stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

Rising inflation rates could negatively impact our business. If our costs increase, our net losses would increase, which may have a material adverse effect on our business.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in decreased demand for our products and services, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our technology and current or future product candidates, or if our intellectual property rights are inadequate, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

Our success depends in part on our ability to obtain and maintain protection for our owned and in-licensed intellectual property rights and proprietary technology. We rely on a combination of patents, trademarks, trade secret protection and confidentiality agreements, including in-licenses of intellectual property rights and biologic materials of others, to protect our current or future platform technologies, product candidates, methods used to manufacture our current or future product candidates and methods for treating patients using our current or future product candidates.

We own or in-license patents and patent applications relating to our platform technologies and product candidates. There is no guarantee that any patents covering our platform technologies or product candidates will issue from the patent applications we own, in-license or may file in the future, or, if they do, that the issued claims will provide adequate protection for our platform technologies or product candidates, or any meaningful competitive advantage. Further, there cannot be any assurance that such patents issued will not be infringed, designed around, invalidated by third parties or effectively prevent others from commercializing competitive technologies, products or product candidates.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner or in countries that could provide meaningful protection. It is also 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 or in-license may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We do not have exclusive control over the preparation, filing and prosecution of patent applications under certain of our in-license agreements, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, that we out-license to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection,

prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

Further, although we make reasonable efforts to ensure patentability of our inventions, we cannot guarantee that all of the potentially relevant prior art relating to our owned or in-licensed patents and patent applications has been found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our product candidates, or the use of our technologies. We thus cannot know with certainty whether we or our licensors were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. There is no assurance that all potentially relevant prior art relating to our owned or in-licensed patent applications has been found. For this reason, and because there is no guarantee that any prior art search is absolutely correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent our owned or in-licensed patent applications from issuing as patents. Invalidation of any of our patent rights, including in-licensed patent rights, could materially harm our business.

Moreover, the patent positions of biotechnology companies like ours are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. The relevant patent laws and their interpretation, both inside and outside of the United States, is also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our platform technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our platform technology, product candidates, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may file or license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Additionally, third parties, including our former employees and collaborators, may challenge the ownership or inventorship of our patent rights to claim that they are entitled to ownership and inventorship interest, and we may not be successful in defending against such claims. However, we are not currently facing any such challenges. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block—in some cases—potential competitors from practicing the claimed inventions of the issued patents.

The issuance, scope, validity, enforceability and commercial value of our pending patent rights are uncertain. The standards applied by the USPTO and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or in-licensed patent applications or narrow the scope of any patent protection we may obtain from our owned or in-licensed patent applications. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that

otherwise may exist for our product candidate and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors or other parties with similar technology. Additionally, our competitors may initiate legal proceedings, such as declaratory judgment actions in federal court or reexaminations or an *inter partes* review at the USPTO in an attempt to invalidate or narrow the scope of our patents. However, we are not currently facing any such proceedings. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Even if patents do successfully issue from our owned or in-licensed patent application, and even if such patents cover our current or any future technologies or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any current or future technologies or product candidates that we may develop. Likewise, if patent applications we own or have in-licensed with respect to our development programs and current or future technologies or product candidates fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future technologies or product candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability. We may be unable to prevent competitors from entering the market with a product that is similar or identical to any of our current or potential future product candidates or from utilizing technologies similar to those in our gene circuit platform technologies.

The filing of a patent application or the issuance of a patent is not conclusive as to its ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our patent applications or patent applications filed by our licensors, or any patents that grant therefrom, may be challenged through third-party submissions, opposition or derivation proceedings. By further example, any issued patents that may result from our owned or in-licensed patent applications may be challenged through reexamination, *inter partes* review or post-grant review proceedings before the USPTO, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our owned or in-licensed patent rights, result in the loss of exclusivity, limit our ability to stop others from using or commercializing similar or identical platforms and product candidates, or allow third parties to compete directly with us without payment to us. In addition, if the breadth or strength of protection provided by any patents that might result from our owned or in-licensed patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future platforms or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, we currently co-own certain patent applications with third parties and may in the future co-own additional patents and patent applications with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent application, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

Our in-licensed patent rights may be subject to a reservation of rights by one or more third parties, such as the U.S. government. In addition, our rights in such inventions may be subject to certain requirements to manufacture

product candidates embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

The patent protection and patent prosecution for some of our product candidates and technologies may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates and technologies, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates and technologies are controlled by our licensors or collaborators. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would.

If any of our licensors or collaborators fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates and technologies, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates and technologies may be adversely affected and we may not be able to prevent competitors from making, using and selling competing product candidates. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our current and future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensed European patents and patent applications could be challenged in the Unified Patent Court, or UPC, for the European Union. Under our current license agreements, we may not have the final or sole decision as to whether we are able to opt out certain of our in-licensed European patents and patent applications from the UPC. Our licensors may decide not to opt out of the UPC, which would subject our in-licensed European patents and patent applications to the jurisdiction of the UPC. Furthermore, even if our licensors decide to opt out of the UPC, we cannot guarantee that our licensors will comply with the legal formalities and requirements for properly opting out of the UPC. Thus, we cannot be certain that our in-licensed European patents and patent applications will not fall under the jurisdiction of the UPC. Under the UPC, a single European patent would be valid and enforceable in numerous European countries. A challenge to the validity of a European patent in a central revocation proceeding under the UPC, if successful, could result in a loss of patent protection in numerous European countries, which could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Further, we may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding(s) or defense activities may be less vigorous than had we conducted them ourselves.

We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

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 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 current or future 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, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Further, our licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Additionally, some intellectual property that we have in-licensed or that we own may have been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government may have the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”).

The U.S. government has the right to take title to these inventions made through government funded programs if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We currently, and in the future may continue to, enter into agreements involving licenses or collaborations that provide for access or sharing of intellectual property. These intellectual property-related agreements may impose certain obligations and restrictions on our ability to develop and commercialize our product candidates and technologies that are the subject of such licenses.

We license rights from third parties to use certain intellectual property relevant to one or more of our current and future product candidates. In the future, we may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our current and future product candidates we may identify and pursue. These existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing,

insurance, patent prosecution and enforcement or other obligations on us. For example, we are a party to three license agreements with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, or NCI, for intellectual property relevant to our product candidates. For a more detailed description of the license agreements with NCI, see the section titled “*Business—Agreements*” in this Form 10-K.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor’s express consent in order for an assignment or transfer to take place.

Further, we or our licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial conditions, results of operations and prospects.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that is the subject of such licensed rights could be materially adversely affected. Even where we have the right to control prosecution of patents and patent applications under license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed currently or in the future from various third parties is or may be subject to retained rights. Our predecessors or licensors do and may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our product candidates, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies and licensed technology into commercial product candidates. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

If we fail to comply with our obligations or disputes arise under any existing or future license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or product candidates or we could lose certain rights to grant sublicenses.

We have certain obligations to third-party licensors from whom we license certain patent rights that are relevant to one or more current and future product candidates. In the future, we may need to obtain additional licenses from other third parties to advance our research and development activities or allow the commercialization of our current and future product candidates. Our existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. For a more detailed description of our existing license agreements, see the section titled “*Business— Our Material Agreements*” in this Form 10-K. If we breach any of these obligations, including diligence obligations with respect to development and commercialization of product candidates covered by the intellectual property licensed to us, or use the intellectual property licensed to us in an unauthorized manner or we are subject to bankruptcy-related proceedings, we may be required to pay damages and the licensor may have the right to terminate the respective agreement or materially modify the terms of the license, such as by rendering currently exclusive licenses non-exclusive. License termination or modification could result in our inability to develop, manufacture and sell products that are covered by the licensed intellectual property or could enable a competitor to gain access to the licensed intellectual property.

Our current or future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor’s intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Disputes may arise between us and our present and future licensors regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues, including but not limited to our right to transfer or assign the license;
- whether and the extent to which our product candidates, technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties, including the terms and conditions thereof;
- our diligence obligations with respect to the development and commercialization of our product candidates that are covered by the license agreement, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- 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 collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the agreements under which we currently license intellectual property or technology from the NCI 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 product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while we currently do not have any liens, security interests, or other encumbrances on the intellectual property that we own, we may, in the future, need to obtain a loan or a line of credit that will require that we put up our intellectual property as collateral to our lenders or creditors. If we do so, and we violate the terms of any such loan or credit agreement, our lenders or creditors may take possession of such intellectual property, including the rights to receive proceeds derived from such intellectual property.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies or product candidates.

Patents have a limited lifespan. The term of individual patents and applications in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. Extensions of patent term may be available, but there is no guarantee that we would have patents eligible for extension, or that we would succeed in obtaining any particular extension, and no guarantee any such extension would confer a patent term for a sufficient period of time to exclude others from commercializing product candidates similar or identical to ours. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the USPTO during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug—and only those claims covering the approved drug, a method for using it or a method for manufacturing it—may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval or applicable approval in other jurisdictions, we expect to apply for patent term extensions on issued patents covering those products in the United States and other jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. We also may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and preclinical data. This could have a material adverse effect on our business and ability to achieve profitability.

The life of a patent and the protection it affords are limited. As a result, our owned and in-licensed patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing product candidates similar or identical to ours. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. For example, given the large amount of time required for the research, development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future technologies or product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law, which could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of any future owned or in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after March 16, 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications. The Leahy-Smith Act also allows third-party submission of prior art to the USPTO during patent prosecution and sets forth additional procedures to challenge the validity of a patent by USPTO-administered post-grant proceedings, including derivation, reexamination, *inter partes* review, post-grant review and interference proceedings. The USPTO developed additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our issued owned or in-licensed patents, all of which could have a material adverse impact on our business prospects and financial condition.

As referenced above, for example, courts in the U.S. continue to refine the heavily fact-and-circumstance-dependent jurisprudence defining the scope of patent protection available for therapeutics, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This creates uncertainty about our ability to obtain patents in the future and the value of such patents. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. We cannot provide assurance that future developments in U.S. Congress, the federal courts and the USPTO will not adversely impact our owned or in-licensed patents or patent applications. The laws and regulations governing patents could change in unpredictable ways that could

weaken our and our licensors' ability to obtain new patents or to enforce our existing owned or in-licensed patents and patents that we might obtain or in-license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may have a material adverse effect on our and our licensors' ability to obtain new patents or to protect and enforce our owned or in-licensed patents or patents that we may obtain or in-license in the future.

We may be subject to lawsuits or litigation to protect or enforce our patents or other intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Third parties may attempt to invalidate our or our licensors' intellectual property rights via procedures including but not limited to patent infringement lawsuits, declaratory judgment actions, interferences, oppositions and *inter partes* reexamination proceedings before the USPTO, U.S. courts and foreign patent offices or foreign courts. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States 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. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action. Even if such rights are not directly challenged, disputes could lead to the weakening of our or our licensors' intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, and could have a material and adverse impact on our profitability, financial condition and prospects or ability to successfully compete.

We or our licensors may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our owned or in-licensed patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to our owned or in-licensed patent or other intellectual property rights, even if resolved in our favor, could be substantial, particularly in a foreign jurisdiction, and any litigation or other proceeding would divert our management's attention. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations.

If we or our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that such patent is invalid or unenforceable. 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, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. 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. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our product candidates or certain aspects of our platform technologies. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our product candidates and technologies if competitors or third parties design around such product candidates and technologies without legally infringing, misappropriating or violating our owned or in-licensed patents or other intellectual property rights.

Our European patents and patent applications could be challenged in the UPC. Though we may decide to opt out our European patents and patent applications from the UPC, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. Potentially, a single proceeding under the UPC could result in loss of patent protection in numerous European countries rather than each validated country separately. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

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

Many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of any owned and in-licensed patents we may obtain in other countries, or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our owned or in-licensed intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put any owned or in-licensed patents at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits or other adversarial proceedings that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our and our licensors' efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects may be materially adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of our potential future collaborators to develop, manufacture, market and sell our current or any future product candidates and to use our proprietary technologies without infringing, misappropriating or violating the proprietary and intellectual property 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 and *inter partes* review proceedings before the USPTO, U.S. courts, foreign

patent offices or foreign courts. As the field of gene and cell therapies advances, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, there is uncertainty as to when, to whom, and with what claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

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. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. Because patent applications can take many years to issue, there may also be currently pending patent applications that may later result in issued patents that our technology or product candidates may infringe. Further, we cannot guarantee that we are aware of all patents and patent applications potentially relevant to our technology or products. We may not be aware of potentially relevant third-party patents or applications for several reasons. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until a patent issues. Patent applications filed in the United States (after November 29, 2000) and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or platform technologies could have been filed by others without our knowledge. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. Additionally, claims pending in patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform, our product candidates or the use of our technologies.

Although no third party has asserted a claim of patent infringement against us as of the date of this Annual Report, others may hold proprietary rights that could prevent our product candidates from being marketed. We or our licensors, or any future strategic collaborator, may be party to, or be threatened with, adversarial proceedings or

litigation regarding intellectual property rights with respect to our current or any potential future product candidates and technologies, including derivation, reexamination, *inter partes* review or post-grant review before the USPTO and similar proceedings in jurisdictions outside of the United States such as opposition proceedings. In some instances, we may be required to indemnify our licensors for the costs associated with any such adversarial proceedings or litigation. Third parties may assert infringement claims against us, our licensors or our strategic collaborators based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic collaborators to enforce or otherwise assert their patent rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are not invalid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our platform technologies or to commercialize our current or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, would invalidate the claims of any such U.S. patent.

Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we, or our licensors, or any future strategic collaborators are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we, or our licensors, or any future strategic collaborators may choose to seek, or be required to seek, a license from a third party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. We could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our platform technologies or product candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Thus, it is possible that one or more third parties will hold patent rights to which we will need a license, which may not be available on reasonable terms or at all. If such third parties refuse to grant us a license to such patent rights on reasonable terms or at all, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing our product candidates, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such case, we may not be able to market such technology or product candidates and may not be able to perform research and development or other activities covered by these patents. This could have a material adverse effect on our ability to commercialize our product candidates and our business and financial condition.

Lastly, if our technology or products are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our shares of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings or developments in

the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or product candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or product candidates, which may not be available on commercially reasonable terms or at all.

Because the gene and cell therapy landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing, misappropriating or violating third-party rights. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Also, our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect.

There are numerous companies that have pending patent applications and issued patents broadly covering gene and cell therapy generally or covering related inventions that may be relevant for product candidates that we wish to develop. We are aware of third-party patents and patent applications that claim aspects of our current or potential future product candidates and modifications that we may need to apply to our current or potential future product candidates. There are also many issued patents that claim inventions that may be relevant to products we wish to develop. The holders of such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current or future technologies, product candidates or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies or product candidates unless we successfully pursue litigation to narrow or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or product candidates. If such an infringement claim should successfully be brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or product candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders may also actively bring infringement, misappropriation, or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or product candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or product candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our current or future technologies and product candidates, we rely on trade secrets, including confidential and unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Our trade secrets include, for example, certain program specific synthesis, formulations, patient selection strategies and certain aspects of our research.

Trade secrets and know-how can be difficult to protect. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to us. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access (such as through a cybersecurity breach) to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, individuals with whom we have such agreements may not comply with their terms. Any of these parties may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breaches. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret, or securing title to an employee-or consultant-developed trade secret if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions disfavor or are unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using the technology or information to compete with us. If, in the future, any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be materially and adversely harmed.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of third parties, including our employees' or consultants' former employers or their clients.

We are party to various contracts under which we are obligated to maintain the confidentiality of trade secrets or other confidential and proprietary information of third parties, including our licensors and strategic partners. In addition, many of our employees or consultants and our licensors' employees or consultants were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that one or more of these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, including former employers of our employees and consultants. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or may be enjoined from using such intellectual property. Any such proceedings and possible aftermath would likely divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are

successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to management.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents as an inventor or co-inventor, or in our trade secrets or other intellectual property as a contributor to its development. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. 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.

Also, our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, 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 condition, results of operations and prospects.

Further, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents or applications and any patent rights we may own or in-license in the future. The USPTO and various non-U.S. patent offices require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these requirements, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse, including due to the effect of a global health emergency such as the COVID-19 pandemic on us, our patent counsel or other applicable patent maintenance vendors, can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within

prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical product candidates or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we use for name recognition by potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, 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 materially adversely affected.

We may also license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

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. The following examples are illustrative:

- others may be able to create gene circuit technologies that are similar to our technologies or our product candidates, but that are not covered by the claims of any patents that we own, license or control;
- we or any strategic collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or control;
- we or our licensors might not have been the first to file patent applications covering certain of our owned and in-licensed inventions;
- others may independently develop the same, similar, or alternative technologies without infringing, misappropriating or violating our owned or in-licensed intellectual property rights;
- it is possible that our owned or in-licensed pending patent applications will not lead to issued patents;
- issued patents that we own, in-license, or control may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such trade secrets or know-how; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

Clinical development includes a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

All of our current product candidates are in preclinical or early clinical development and their risk of failure is high. It is impossible to predict when or if our candidates or any potential future product candidates will prove effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies for our current product candidates and then conduct extensive clinical trials to demonstrate the safety, purity and potency, or efficacy of that product candidate in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process. The results of preclinical studies and clinical trials of any of our current or potential future product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

We may experience delays in completing our preclinical studies and initiating or completing our clinical studies. We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- the FDA or other regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to initiate a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective 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;
- obtaining IRB or ethics committee approval at each clinical trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the FDA placing the clinical trial on hold;

- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse events;
- any changes to our manufacturing process that may be necessary or desired;
- adding new clinical trial sites; and
- manufacturing sufficient quantities of our product candidates for use in clinical trials.

Furthermore, we expect to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our current or potential future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities 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 drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and 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 a regulatory authority 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 the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of any of our current or potential future product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may have a material adverse effect on our business, financial condition, results of operations and prospects. 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 current or potential future product candidates.

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize our current or potential future product candidates.

Our current and any potential future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval,

recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our potential future collaborators to begin selling them.

We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and other regulatory authorities. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in regulatory policy during the period of product development, clinical trials and FDA regulatory review in the United States and other jurisdictions. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Further, we and our potential future collaborators may never receive approval to market and commercialize any product candidate. Even if we or a potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

Once a product obtains regulatory approval, numerous post approval requirements apply, including periodic monitoring and reporting obligations, review of promotional material, reports on ongoing clinical trials and adverse events and inspections of manufacturing facilities. In addition, material changes to approved products, including any changes to the manufacturing process or labeling, require further review by the appropriate authorities before marketing. Approvals may also be withdrawn or revoked due to safety, effectiveness or potency concerns, including as a result of adverse events reported in patients or ongoing clinical trials, or failure to comply with cGMP. In addition to revocation or withdrawal of approvals, we and our partners may be subject to warnings, fines, recalls, criminal prosecution or other sanctions if we fail to comply with regulatory requirements. If we or our partners are unable to obtain or maintain regulatory approvals for our products and product candidates, our business, financial position, results of operations and future growth prospects will be negatively impacted and we or our partners may be subject to sanctions. If any of our product candidates prove to be ineffective, unsafe or commercially unviable, we may have to re-engineer our current or potential future product candidates, and our entire pipeline could have little, if any, value, which could require us to change our focus and approach to product candidate discovery and therapeutic development, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We will also be subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

If we succeed in developing any products, we intend to market them in the United States as well as the European Union and other foreign jurisdictions. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates will be harmed.

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

We may choose to conduct one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless (i) those data are applicable to the U.S. population and U.S. medical practice; (ii) the studies were performed by clinical investigators of recognized competence; and (iii) 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 studies 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 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. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. 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.

Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

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

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

Any regulatory approvals that we or potential future collaborators obtain for any of our current or potential future product candidates will be subject to limitations on the approved indicated uses for which a product may be marketed or may be subject to the conditions of approval, or contain requirements for potentially costly post-marketing testing, and surveillance to monitor the safety and efficacy of such product candidate. In addition, if the FDA or any other regulatory authority approves any of our current or potential future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for such product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practices for any clinical trials that we conduct post-approval. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including registering their establishments with the FDA and certain state agencies, ensuring that quality control and manufacturing procedures conform to cGMP and cGTP regulations and applicable product tracking and tracing requirements. Manufacturing facilities are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other regulatory requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions.

Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product candidate, withdrawal of the product candidate from the market or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic collaborators;
- suspension or revocation of product approvals;

- suspension of any ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties or monetary fines.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy (“REMS”) as part of a biologics license application, or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

Furthermore, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off-label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict a manufacturer’s communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion.

The FDA and other regulatory authorities have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act 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-licensed 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 licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex. The BPCIA could have a material adverse effect on the future commercial prospects for our biological products.

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

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our product candidates profitably, if approved. Among policy-makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems, with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. See section titled “*Business - Government Regulation – Healthcare Reform*” in this Form 10-K.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services to contain or reduce the costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- our ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and to restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA 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 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.

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, if approved. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted 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.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost

containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other sensitive information to develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes.

We and any potential future collaborators, partners or service providers may be subject to federal, state and foreign data protection laws, regulations and regulatory guidance, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or contractual obligations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, such as the Health Insurance Portability and Accountability Act (“HIPAA”), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of any future potential collaborators or service providers.

In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, or if we otherwise violate applicable privacy and data security laws.

International data protection laws may also apply to health-related and other personal information obtained outside of the United States. With respect to Europe, we are subject to the GDPR, as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018), where we are collecting or otherwise processing personal data (including health data) in connection with (a) the offering of goods or services to/the monitoring of the behavior of individuals in the EEA/UK; or (b) the activities of a business establishment in the EEA/UK. The UK’s data protection regime is independent from but aligned to the EU’s data protection regime. The GDPR imposes stringent data protection requirements for processing personal data of individuals within the EEA, and the UK, as well as potential fines for noncompliant companies of up to the greater of €20 million (£17.5 million for the UK GDPR) or 4% of annual global revenue, and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

In addition, the GDPR places restrictions on cross-border transfers of personal data to countries outside the EEA/UK that do not ensure an adequate level of protection, including the United States in certain circumstances, unless a derogation exists or a valid GDPR transfer mechanism is put in place and transfer impact assessments carried out to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal information under the GDPR, including an analysis of the laws in the recipient’s country. The international transfer obligations under European data protection laws will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and UK personal data is transferred and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our operations and may adversely affect our business and financial position.. The international transfer obligations under European data protection laws may also impact our business as companies based in Europe may be reluctant to utilize the GDPR transfer mechanisms to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the GDPR transfer mechanisms impose upon exporters.

If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

The GDPR has increased our responsibilities and potential liability in relation to personal data processed subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. In addition, any failure by us (or our business partners who handle personal data) to comply with GDPR and applicable laws and regulations relating to privacy and data protection of EEA member states and the UK may result in regulators prohibiting our processing of the personal data of EEA and UK data subjects, which could impact our operations and ability to develop our products and provide our services, including interrupting or ending EEA and UK clinical trials.

Following the UK's exit from the EU, or Brexit, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the UK has recently introduced the Data Reform Bill into the UK legislative process with the intention for this bill to reform the UK's data protection regime following Brexit. If passed, the final version of the effect Data Reform Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK adequacy decision from the EU Commission which allows the free flow of personal data from the UK to the EEA. This may lead to additional compliance costs and could increase our overall risk. This lack of clarity on future UK laws and regulations and their interaction with those of the EU could add legal risk, uncertainty, complexity, and cost to our handling of European personal data and our privacy and security compliance programs, and may require us to implement different compliance measures for the UK and EEA. In addition, EEA Member States have adopted national laws to implement the EU GDPR that may partially deviate from the EU GDPR and competent authorities in the EEA Member States may interpret the EU GDPR obligations slightly differently from country to country. Therefore, we do not expect to operate in a uniform legal landscape in the EEA.

In the U.S., state laws also govern the privacy and security of personal information and states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the "CCPA") gives California residents expanded rights to access, correct, and delete their personal information, opt out of certain personal information sharing and certain uses of sensitive data, and receive detailed information about how their personal information is used by requiring covered companies to provide disclosures to California consumers (as that term is broadly defined and includes any of our current or future employees who may be California residents) and provide such residents ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches and statutory damages, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgments and settlements. It will also create a new California data protection agency authorized to issue substantive regulations which could result in increased privacy and information security enforcement. Although the law includes limited exceptions for health-related information, including clinical trial data, such exceptions may not apply to all of our operations and processing activities. As we expand our operations and trials (both preclinical and clinical), the CCPA may increase our compliance costs and potential liability. Beyond the CCPA, broad and comprehensive privacy and data protection legislation has been passed in another twelve states. In addition, certain states have passed privacy laws focused on particular types of data. For example, the state of Washington has enacted a law that protects the privacy of health and medical information not subject to HIPAA and a small number of states have laws that apply specifically to biometric information. Furthermore, other U.S. states, such as New York, Massachusetts, and Utah, have enacted stringent data security laws, and numerous other states have proposed similar privacy laws. In the event that we are subject to or affected by HIPAA, the GDPR, the CCPA 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.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Laws and regulations worldwide relating to privacy, data protection and cybersecurity are, and are likely to remain, uncertain for the foreseeable future. While we strive to comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity to the extent possible, we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel, collaborators, partners or vendors do not comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity. Actual or perceived failure to comply with any laws and regulations relating to privacy, data protection or cybersecurity in the U.S. or foreign jurisdictions could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators or service providers obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with applicable laws or regulations, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, result in regulatory actions and proceedings, in addition to private claims and litigation, and could result in adverse publicity that could harm our business.

We also are, or may be asserted to be, subject to the terms of our external and internal privacy and security policies, representations, certifications, publications and frameworks and contractual obligations to third parties related to privacy, data protection, information security and processing. Failure to comply or the perceived failure to comply with any of these, or if any of these policies or any of our representations, certifications, publications or frameworks are, in whole or part, found or perceived to be inaccurate, incomplete, deceptive, unfair or misrepresentative of our actual practices, could result in reputational harm, result in litigation, cause a material adverse impact to business operations or financial results and otherwise result in other material harm to our business.

If we or our existing or potential future collaborators, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates and may harm our reputation.

Healthcare providers, physicians and third-party payors, among others, will play a primary role in the prescription and recommendation of any product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. See section titled "Business - Government Regulation - Other U.S. Healthcare Laws" in this Form 10-K.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry.

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 do 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 administrative, civil, and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual

imprisonment, reputational harm, and curtailment or restructuring of our operations, as well as 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. Further, defending against any such actions can be costly and time consuming, and may require significant financial and 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. 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 exclusion from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the United States and any foreign jurisdiction in which we seek regulatory approval. The FDA and other regulatory authorities have significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product candidate from the market. The FDA and other regulatory authorities also have the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMP and cGTP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product candidate, manufacturer or facility, including withdrawal of the product candidate from the market. We intend to rely on third-party manufacturers and we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the U.S. or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Further, due to the COVID-19 pandemic, millions of individuals have lost employer-based insurance coverage, which may adversely affect our ability to commercialize our products. It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals. See section titled “*Business - Government Regulation - Coverage and Reimbursement*” in this Form 10-K.

Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated

with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

Cost-containment is a priority in the U.S. healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its product. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U.S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted a Code of Business Conduct and Ethics and we expect to prepare and implement policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or

governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Risks Related to Senti and the shares of our common stock

Our stock price is volatile, and you could lose part of all of your investment.

Similar to the trading prices of the common stock of other biotechnology companies, the trading price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our shares of our Common Stock may be influenced by many factors, including the other risks described in the section of this 10-K entitled "*Risk Factors*" and the following:

- our ability to advance our current or potential future product candidates into the clinic and through
- results of preclinical studies and clinical trials for our current or potential future product candidates, or those of our competitors or potential future collaborators;
- the impact of macroeconomic conditions;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our future products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization collaborators, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory authorities with respect to our future products, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including, but not limited to, those with any sources of manufacturing supply and future commercialization collaborators;
- market conditions in the pharmaceutical and biotechnology sectors;
- market conditions and sentiment involving companies that have recently completed a business combination with a special purpose acquisition company, or SPAC;
- announcements by us or our competitors of significant acquisitions, strategic alliances, joint ventures or capital commitments;

- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which it is raised;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or the industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of shares of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of shares of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, public health crises and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for SPAC post-Merger businesses, pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility. This volatility can often be unrelated to the operating performance of the underlying business. These broad market and industry factors may seriously harm the market price of shares of our common stock, regardless of our operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

We may incur significant costs from class action litigation due to the expected stock volatility.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of development efforts for our platform and product candidates, the development efforts of future collaborators or competitors, the addition or departure of key personnel, variations in quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years, including since the public announcement of the Business Combination Agreement in December 2021. In addition, recently there has been significant stock price volatility involving the shares of companies that have recently completed a Merger with a SPAC. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. Additionally, there has recently been a general increase in litigation against companies that have recently completed a Merger with a SPAC alleging fraud and other claims based on inaccurate or misleading disclosures. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of management.

We are an “emerging growth company” and it cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the shares of our common stock less attractive to investors and may make it more difficult to compare performance with other public companies.

We are an emerging growth company as defined in the JOBS Act, and we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may find shares of our common stock less attractive because we will continue to rely on these exemptions. If some investors find our shares of our common stock less attractive as a result, there may be a less active trading market for their common stock, and the stock price may be more volatile.

An emerging growth company may elect to delay the adoption of new or revised accounting standards. With DYNs making this election, Section 102(b)(2) of the JOBS Act allows us to delay adoption of new or revised accounting standards until those standards apply to non-public business entities.

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

As a result, the financial statements contained in this Annual Report and those that we will file in the future may not be comparable to companies that comply with public business entities revised accounting standards effective dates.

If certain holders of our common stock sell a significant portion of their securities, it may negatively impact the market price of the shares of our common stock and such holders still may receive significant proceeds.

As of the date of this Annual Report on Form 10-K, the market price of our common stock is below \$10.00 per share, which was the price per share of common stock sold in the initial public offering of our predecessor, DYNs, the per share price of the 5,060,000 shares of our Common Stock sold to certain investors in connection with our PIPE financing and also the per share value of the consideration issued to former stockholders of Senti Sub I, Inc. (formerly Senti Biosciences, Inc.) upon consummation of our Merger. However, certain of our stockholders who hold shares of our common stock that were (i) originally purchased by our predecessor’s sponsor, Dynamics Sponsor LLC, in a private placement prior to our predecessor’s initial public offering (the “Founder Shares”) or (ii) issued to the Anchor Investors in consideration for their agreement not to redeem their shares of Class A common stock of DYNs in connection with the Merger. In particular, 4,878,972 of the Founder Shares registered for resale in our prospectus dated August 8, 2022 filed pursuant to Rule 424(b)(3) (Registration No. 333-265873), as supplemented from time to time (the “Prior Resale Prospectus”), were purchased at an effective price of \$0.004 per share, and

871,028 of the shares of our common stock held by the Anchor Investors and registered for resale in the Prior Resale Prospectus were issued solely in consideration for the Anchor Investors' agreement not to redeem their shares of Class A common stock as described above. Accordingly, holders of these 5,750,000 shares of our common stock could sell their securities at a per share price that is less than \$10.00 and still realize a significant return from the sale of those securities that could not be realized by our other stockholders. On March 18, 2024, the closing price of our common stock as reported on the Nasdaq Capital Market was \$0.40 per share. Based on this closing price, the aggregate sales price of the Founder Shares would be approximately \$2.0 million and the aggregate sales price of the shares of our common stock held by the Anchor Investors would be approximately \$0.3 million.

Sales of a substantial number of shares of our common stock in the public market could cause our stock prices to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

Certain holders of our common stock have rights, subject to 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. We have also filed registration statements on Form S-8 registering shares of common stock issued or reserved for future issuance under our equity compensation plans. Shares registered under a registration statement on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Significant additional capital will be needed in the future to continue our planned operations, including further development of our gene circuit platform, preparing IND or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner as determined from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of shares of our common stock. For a more detailed description of our equity financing through sale of common shares to Chardan under the Purchase Agreement, see the Risk Factors titled "*It is not possible to predict the number of shares of our common stock, if any, that we may sell to Chardan Capital Markets LLC, or Chardan, under our common stock Purchase Agreement, or the Purchase Agreement, with Chardan, or the actual gross proceeds resulting from those sales, or the dilution to our stockholders from those sales*" and "*The sale or issuance of shares of our common stock to Chardan will result in additional outstanding shares and the resale of shares of our common stock by Chardan that it acquires pursuant to the Purchase Agreement, or the perception that such sales may occur, could cause the price of shares of our common stock to decrease*" in this Form 10-K.

Pursuant to the Senti Biosciences, Inc. Equity Incentive Plan, our board of directors or compensation committee is authorized to grant stock options to our employees, directors and consultants. Initially, the maximum aggregate number of shares of our common stock that may be issued pursuant to stock awards under the Incentive Plan was 2,492,735 shares of our common stock. Additionally, the number of shares of our common stock reserved for issuance under the Incentive Plan automatically increases on January 1 of each year, beginning on January 1, 2023 and continuing through and including January 1, 2032, by 5% of the total number of shares of our common stock

outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. In addition, on August 5, 2022, our board of directors adopted the 2022 Inducement Plan, pursuant to which an aggregate of 2,000,000 shares of our common stock have been reserved for issuance. Our issuance of additional shares of common stock or other equity securities of equal or senior rank would, all else being equal, have the following effects:

- the amount of cash available per share, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding share of common stock would be diminished; and
- the market price of shares of our common stock may decline.

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

We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of shares of our common stock.

We currently expect that securities research analysts will establish and publish their own periodic financial projections for our business. These projections may vary widely and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect research analyst coverage, if no analysts commence coverage of us, the trading price and volume for shares of our common stock could be adversely affected.

The obligations associated with being a public company involve significant expenses and require significant resources and management attention, which may divert from our business operations.

As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. As a result, we currently incur, and expect to continue to incur, significant legal, accounting and other expenses to comply with our obligations as a public company. Our entire management team and many of our other employees will need to devote substantial time to compliance, and may not effectively or efficiently manage our transition into a public company.

These rules and regulations will result in us incurring substantial legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations will likely make it

more difficult and 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 difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

Provisions in our second amended and restated certificate of incorporation (“Charter”), our amended and restated bylaws, or Bylaws, and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management, which could depress the trading price of shares of our common stock.

Our Charter, Bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our Charter and Bylaws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms, such that not all members of the board will be elected at one time;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our Bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our Charter and Bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. 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 shares of our common stock.

In addition, because we are incorporated in the State of 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.

Any provision of our Charter, Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for shares of our common stock.

Our Bylaws designate the Court of Chancery of the State of Delaware as the exclusive forum for certain state law litigation that may be initiated by our stockholders and the U.S. federal district courts as the exclusive forum for certain securities law actions, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum and increase the costs for our stockholders to pursue certain claims against us.

Pursuant to our Bylaws, 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 the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our Charter or our Bylaws (including their interpretation, validity or enforceability); or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Stockholders cannot waive compliance with the Securities Act, the Exchange Act or any other federal securities laws or the rules and regulations thereunder. Unless we consent in writing to the selection of an alternate forum, the United States federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these exclusive forum provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder. The forum selection provisions in our Bylaws may impose additional litigation costs on stockholders in pursuing any such claims and may limit our stockholders' ability to litigate disputes with us in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce the federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

On August 7, 2023, we received written notice from the Listing Qualifications Department of Nasdaq ("Nasdaq") notifying us that, for the last 30 consecutive trading days, the closing bid price of our common stock was below the minimum bid price requirement of \$1.00 per share for continued listing on the Nasdaq Global Market, i.e., the minimum closing bid price requirement. We have been provided an initial compliance period of 180 calendar days, or until February 5, 2024 to regain compliance with the minimum closing bid price requirement.

On January 23, 2024, we were notified by Nasdaq that Nasdaq had granted our request to transfer the listing of our common stock from the Nasdaq Global Market tier to the Nasdaq Capital Market tier, effective January 25, 2024. The transfer of the listing of our common stock from The Nasdaq Global Market to The Nasdaq Capital Market took effect with the open of business on January 25, 2024.

On February 6, 2024, Nasdaq granted our request for a second 180-calendar day period, or until August 5, 2024 to regain compliance with the \$1.00 bid price requirement. To regain compliance with such minimum price requirement, we must evidence a closing bid price of at least \$1.00 per share for a minimum of 10 consecutive business days.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider taking actions to regain compliance with the minimum closing bid price requirement. There can be no assurance that we will be

able to regain compliance with the minimum closing bid price requirement or will otherwise be in compliance with other applicable Nasdaq listing rules.

If we fail to satisfy the continued listing requirements of Nasdaq such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future.

We may be at an increased risk of securities class action litigation.

Historically, 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 biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

Disruptions at the FDA and other government agencies, such as those caused by funding shortages, could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent those agencies from performing normal business functions on which operations of our business may rely, and/or 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, government funding of the SEC and other government agencies on which our operations and fundraising may rely, including those that fund research and development activities and regulate our access to public markets, 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 drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the past decade, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submission, which could have a material adverse effect on our business.

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.

Our current operations are located in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemics, including any lingering effects from the global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our headquarters, or the manufacturing facilities of our third-party contract manufacturers, may have a material adverse effect on our ability to operate our business, particularly on a daily basis and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics, such as the recent COVID-19 outbreak could further disrupt our operations and have a material adverse effect on our business, financial condition, results of operations 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 our research facilities or the manufacturing facilities of our third-party contract manufacturers, 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. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our headquarters or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial condition, results of operations and prospects.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies and clinical trials or funding support by us or potential future collaborators;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any of our existing or potential future collaboration, licensing or similar arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;

- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cyber Risk Management and Strategy

We have adopted cybersecurity risk management processes that are informed by and incorporate elements of recognized industry standards, such as the National Institute of Standards and Technology Cybersecurity Framework, and that are designed to identify, assess, and mitigate critical risks from cybersecurity threats.

To support our cybersecurity risk management processes, we leverage a third-party Information Security Coordinator who provides ongoing support for the protection of our information technology infrastructure and also engage with other third-party providers and cybersecurity consultants as appropriate, including engagement of third parties to assist with managed detection and response. Additionally, our cybersecurity risk management strategy is informed by a recent risk assessment conducted by a third-party cybersecurity consultant.

We have an employee security awareness training program, required upon onboarding and on an annual basis thereafter, that is designed to raise awareness of cybersecurity threats across functions as well as to encourage consideration of cybersecurity risks across our Company. As part of this employee training program, we periodically conduct phishing simulations designed to raise employee awareness of such risks.

We have also implemented a process to assess and review the cybersecurity practices of certain third-party vendors and service providers, such as software-as-a-service providers whose products are used to store our data, including through review of System and Organization Controls (SOC) reports prior to onboarding.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems and infrastructure. For more information, please see Item 1A - Risk Factors.

Governance Related to Cybersecurity Risks

Our Information Security Coordinator is responsible for the establishment and maintenance of our cybersecurity risk management processes, including the day-to-day oversight of the assessment and management of cybersecurity risks. The individual who is currently in this role has approximately 20 years of experience in information security. Our Information Security Coordinator reports to, and meets periodically with, our Director of Operations to discuss and review our information security and cybersecurity risk management processes.

Our board of directors has delegated oversight of the Company's enterprise risk management processes, including those related to cybersecurity risks, to the audit committee of the board of directors. We have implemented a process for our Information Security Coordinator, as appropriate, to provide periodic updates to the audit committee on the status of our cybersecurity program.

Item 2. Properties

Our corporate headquarters is located in South San Francisco, California, where we lease approximately 40,000 square feet of office and research and development space pursuant to a lease agreement which commenced on April 25, 2019 and expires on April 30, 2027, with an option to extend for eight years. In Alameda, California, we lease approximately 92,000 square feet of space pursuant to a lease agreement which initiated on June 3, 2021 and expires on September 30, 2032, with two options to extend for five years each. We completed the build-out of a cell therapy manufacturing facility designed to meet cGMP in the Alameda facility in June 2023, and in August 2023, we subleased our the Alameda cGMP facility to GeneFab as part of our transaction with GeneFab.

Item 3. Legal Proceedings

From time to time we may become involved in legal proceedings to claims arising in the ordinary course of our business. We are not currently a party to any such material legal proceedings.

Item 4. Mine Safety Disclosures

None.

PART II

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

Market Information

Our common stock is currently listed on The Nasdaq Capital Market under the symbol “SNTI”, and was previously traded under the same symbol on The Nasdaq Global Market. Prior to the consummation of the Merger, our common stock was listed on The Nasdaq Global Market under the symbol “DYNS.”

Holdings

As of March 18, 2024, there were 63 holders of record of our common stock. The number of holders of record does not include for example a substantially greater number of “street name” holders or beneficial holders whose Senti Common Shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have not paid any cash dividends to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our board of directors at such time. Our ability to declare dividends may also be limited by restrictive covenants pursuant to any future debt financing agreements.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

Pursuant to Chardan’s committed equity facility, we issued and sold 1,000,000 shares of our common stock to Chardan at a weighted average price of \$0.51 per share during the year ended December 31, 2023. We used the net proceeds from these sales for general corporate purposes.

In Chardan’s committed equity facility, Chardan represented to us, among other things, that it is an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act). The shares of common stock referred to in this Annual Report on Form 10-K were issued and sold by us to Chardan in reliance upon the exemptions from the registration requirements of the Securities Act afforded by Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D promulgated thereunder.

Item 6. [RESERVED]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Senti Biosciences, Inc. (“Senti”) entered into a business combination agreement (the “Agreement”) with Dynamics Special Purpose Corp. (“DYNS”) on December 19, 2021. The transactions contemplated by the terms of the Agreement were completed on June 8, 2022 (the “Closing”), in conjunction with which DYNS changed its name to Senti Biosciences, Inc. (hereafter referred to, collectively with its subsidiaries, as “Senti”, the “Company”, “we”, “us” or “our”, unless the context otherwise requires). The transactions contemplated in the Agreement are collectively referred to as the “Merger”. You should read the following discussion and analysis of our financial condition and results of operations together with our accompanying consolidated financial statements and the related notes contained in Part II, Item 8 of this Annual Report on Form 10-K. Unless the context indicates otherwise, references in this Annual Report on Form 10-K to the “Company,” “Senti,” “we,” “us,” “our” and similar terms refer to Senti Biosciences, Inc. (formerly known as Dynamics Special Purpose Corp.) and its consolidated subsidiaries following the Company’s Merger.

Cautionary Statement Regarding Forward-Looking Statements

This Annual Report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that are not historical facts and involve risks and uncertainties that could cause actual results to differ materially from those expected and projected. All statements, other than statements of historical fact included in this Form 10-K including, without limitation, statements in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations” regarding the Company’s financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. Words such as “expect,” “believe,” “anticipate,” “explore,” “intend,” “estimate,” “seek” and variations and similar words and expressions are intended to identify such forward-looking statements. Such forward-looking statements relate to future events or future performance, but reflect management’s current beliefs, based on information currently available. A number of factors could cause actual events, performance or results to differ materially from the events, performance and results discussed in the forward-looking statements. For information identifying important factors that could cause actual results to differ materially from those anticipated in the forward-looking statements, please refer to the Risk Factors section of the Annual Report Part I, Item 1A of this Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”). The Company’s securities filings can be accessed on the EDGAR section of the SEC’s website at www.sec.gov. Except as expressly required by applicable securities law, the Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

Overview

Senti is an early clinical stage biotechnology company developing next-generation cell and gene therapies engineered with its gene circuit platform technologies for patients living with incurable diseases. Senti’s mission is to create a new generation of smarter therapies that can outsmart complex diseases using novel and unprecedented approaches. To accomplish this mission, Senti has built a synthetic biology platform that it believes may enable it to program next-generation cell and gene therapies with gene circuits. These gene circuits, which Senti created from novel and proprietary combinations of DNA sequences, are designed to reprogram cells with biological logic to sense inputs, compute decisions and respond to their respective cellular environments. Using gene circuits, Senti’s product candidates are designed to precisely kill cancer cells, spare healthy cells, increase specificity to target cells and control the expression of drugs even after administration. Senti is applying its gene circuit technologies to develop a pipeline of medicines that use off-the-shelf chimeric antigen receptor natural killer (“CAR-NK”) cells with the goal of addressing major challenges and providing potentially lifesaving treatments for people living with cancer. Senti’s lead product candidates utilize off-the-shelf healthy adult donor derived NK cells to create CAR-NK cells outfitted with its gene circuit technologies in several oncology indications with high unmet need.

We have incurred net losses of \$71.1 million and \$58.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, we had cash, cash equivalents, and short-term investments, of \$35.9 million and \$98.6 million, respectively, and an accumulated deficit of \$244.3 million and \$173.3 million, respectively. Net cash flows used in operating activities were \$52.4 million and \$34.9 million during the years ended December 31, 2023 and 2022, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and impairment of the Company’s long-lived assets. We expect to continue to incur significant losses for the foreseeable future.

We anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be driven in large part by our ongoing activities, if and as we:

- continue to advance our gene circuit platform technologies;
- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- fund clinical development of our current product candidates;
- commence clinical studies of our future product candidates;
- fund manufacturing of our current and future product candidates;

- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing and commercialization efforts;
- continue to develop, grow, maintain, enforce and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

As of March 21, 2024, the issuance date of the consolidated financial statements for the year ended December 31, 2023, the Company concluded that substantial doubt existed about the Company's ability to continue as a going concern beyond twelve months from the issuance date of the annual consolidated financial statements. In light of these concerns, our independent registered public accounting firm included in its opinion for the year ended December 31, 2023 an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern beyond twelve months from March 21, 2024.

Recent Developments

On August 7, 2023, we completed a transaction with GeneFab, LLC ("GeneFab"), a contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. We sold, assigned and transferred rights, title and interest in certain of our assets and contractual rights, including all of our equipment at our facilities in Alameda and certain of our intellectual property related to the schematics for and design of the Alameda facility. We subleased our recently constructed 92,000 square foot current good manufacturing practice facility in Alameda, California to GeneFab which will support the clinical manufacturing of our CAR-NK programs, including SENTI-202. The transaction provided us with additional capital in the form of a note receivable and rights to future manufacturing and research activities and reduced longer term operating expenses. In connection with the transaction, we are entitled to receive total consideration of \$37.8 million before the end of 2025, of which \$18.9 million was due at closing and was netted against prepayment owed by us for manufacturing and research activities to GeneFab. The remaining \$18.9 million will be paid to us in installments in 2024 and 2025, subject to satisfaction of certain conditions. The Company determined that the \$18.9 million for future manufacturing and research activities, inclusive of the volume discount provided, was executed at market terms and does not result in any impact to the total consideration received from GeneFab for the disposal of the business.

We also agreed to grant a license to GeneFab under certain of our intellectual property rights to conduct manufacturing services and to research, develop, manufacture and commercialize products outside of oncology, pursuant to a license agreement under negotiation.

GeneFab was provided an option to purchase up to 19,633,444 shares (i.e. up to \$20.0 million worth) of our common stock at an exercise price of \$1.01867 (the "GeneFab Option"). The GeneFab Option becomes exercisable upon the execution of the license agreement, no later than August 7, 2026. The GeneFab Option may be exercised in installments of common stock equal to no more than 19.9% of our outstanding shares of common stock as of the closing date of the transaction.

As additional consideration for the transaction, we entered into a seller economic share agreement with GeneFab ("GeneFab Economic Share"), pursuant to which we will be entitled to receive ten percent of the realized gains of GeneFab's parent company arising and resulting from any cash or in-kind distributions from GeneFab in connection with a dividend or sale event, subject to the terms and conditions of the GeneFab Economic Share.

As the assets and contractual rights transferred to GeneFab were determined to constitute a business as defined in ASC 805, *Business Combinations*, we accounted for the disposal by applying the derecognition guidance in ASC 810, *Consolidations*, which requires that a gain or loss be recognized for the difference between the carrying value of the assets sold and the fair value of the consideration received (or receivable). In connection with the sale, we recognized a gain on disposal in the amount of \$21.9 million in net income from discontinued operations during the year ended December 31, 2023, representing the excess of the fair value of the consideration received and receivable (net of the portion allocated to the GeneFab Option) over the carrying value of the assets sold. The gain on disposal was primarily related to the grant of the non-oncology license to GeneFab which had no carrying value.

In accordance with ASC 205, *Presentation of Financial Statements*, we determined that the disposal of the non-oncology business, including the equipment and transfer of in-house manufacturing services in the Alameda facility, represented a strategic shift that will have a major effect on our operations and financial results, thus meeting the criteria to be reported as discontinued operations. As a result, we have retrospectively restated our consolidated balance sheet at December 31, 2022 and consolidated statements of operations and comprehensive loss for the year ended December 31, 2022 to reflect the assets and liabilities and operating results, respectively, related to the disposed business in discontinued operations. We have chosen not to segregate the cash flows of the disposed business in the consolidated statements of cash flows. Supplemental disclosures related to discontinued operations for the statements of cash flows have been provided in Note 4. *GeneFab Transaction* to our consolidated financial statements. Unless otherwise specified, the results of operations refer to continuing operations only.

In November 2023, the Company entered into a Collaboration and Option Agreement with Celest Therapeutics (Shanghai) Co. Ltd. (“Celest”). Subject to the terms and conditions of the Agreement, the Company and Celest will enter into a collaboration under which Celest will lead a pilot trial of a candidate product for our SENTI-301A program in mainland China, with certain technical support from the Company. In addition, the Company agreed to grant an exclusive option to enter a license agreement with Celest to research, develop, manufacture and commercialize SENTI-301A in mainland China, Hong Kong, Macau, and Taiwan. Outside of these jurisdictions, the Company would retain its rights in the SENTI-301A program. Pursuant to the Agreement, and beginning with the exercise of the option and entering into a license agreement, the Company may become eligible to receive certain option exercise fee and milestone payments, in an aggregate amount of \$156 million, as well as certain tiered royalty payments.

In January 2023 we announced a strategic plan to focus internal resources on SENTI-202 and SENTI-404, to develop gene circuits for other programs with potential partners, and to suspend research and development efforts for SENTI-301A. In January 2024, we announced a strategic plan to streamline business operations and focus our resource allocation to investment on clinical development of SENTI-202, for which an Investigational New Drug (IND) application was cleared by the U.S. Food and Drug Administration (“FDA”) in December 2023, and on the partnership of our SENTI-301A program in China with Celest.

Components of Results of Operations

Total Revenue

We currently have no therapeutic products approved for sale, and we have never generated any revenue from the sale of any therapeutic products. Total revenue consists of contract revenue related to research services provided to customers and grant income which is research funding received from grants.

Our ability to generate product revenues will depend on our partners’ ability to replicate our results and the successful development and eventual commercialization of our product candidates, which we do not expect for the foreseeable future, if ever. We may also look to generate revenue from collaboration and license agreements in the future.

Operating Expenses

Our operating expenses consist of research and development expenses, general and administrative expenses, and impairment of long-lived assets.

Research and Development Expenses

Research and development costs consist primarily of costs incurred for the discovery, preclinical and clinical development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation expenses for employees engaged in research and development functions;
- expenses incurred in connection with research, laboratory consumables and clinical and preclinical studies;
- the cost of consultants engaged in research and development, regulatory, and clinical related services

- the cost to develop our manufacturing process and manufacturing product candidates for use in our research, preclinical studies and clinical trials, including under agreements with third parties, such as consultants, contractors and CMOs;
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs related to regulatory compliance; and
- the cost of annual license fees.

We have not historically tracked research and development expenses by program, with the exception of third-party research projects. Our internal resources, employees and infrastructure are not directly tied to any one research or product candidate project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for these early-stage research and product candidate discovery programs on a project-specific basis.

Our direct external development program expenses reflect external costs attributable to our preclinical development candidates selected for further development as well as investigational new drug applications (“INDs”) and clinical development activities. Such expenses include third-party contract costs relating to manufacturing, clinical trial activities, translational medicine and toxicology activities. We do not allocate internal research and development costs which include personnel, facility costs, laboratory consumables and discovery and research related activities associated with our pipeline because these costs are deployed across multiple programs and our platform, and, as such, are not separately classified.

Our research and development expenses related to the assets sold to GeneFab are included in discontinued operations.

Research and development expenses consisted of the following (in thousands):

	Years Ended December 31,	
	2023	2022
External services and supplies	\$ 13,247	\$ 11,524
Personnel-related expenses, including share-based compensation expense	10,508	8,570
Office and facilities	7,316	7,274
Other	1,079	777
Total	\$ 32,150	\$ 28,145

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our preclinical development programs. Product candidates in clinical development generally have higher development costs than those in preclinical stages of development, primarily due to the increased size and duration of clinical trials. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical development of any of our product candidates.

The successful development of our current and future product candidates is highly uncertain. This is due to numerous risks and uncertainties, including the following:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon any or all of our programs;
- product-related side effects experienced by participants in our clinical trials or by individuals using therapeutics similar to our product candidates;

- delays in submitting IND applications or comparable foreign applications, or delays or failures to obtain the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or other regulatory authorities regarding the scope or design of our clinical trials
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- Chemistry, manufacturing and control (“CMC”) challenges associated with manufacturing and scaling up biologic product candidates to ensure consistent quality, stability, purity and potency among different batches used in clinical trials;
- greater-than-anticipated clinical trial costs;
- poor potency or effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory authority inspection and review of a clinical trial or manufacturing site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; and
- the FDA or other regulatory authorities interpret our data differently than we do.

A change in the outcome of any of these variables may significantly impact the costs and timing associated with the development of our product candidates. 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 employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to corporate matters, professional fees for accounting and consulting services and an allocation of facility-related costs.

Our general and administrative costs related to the assets sold to GeneFab are included in discontinued operations.

General and administrative expenses consisted of the following (in thousands):

	Years Ended December 31,	
	2023	2022
Personnel-related expenses, including share-based compensation expense	\$ 23,117	\$ 27,512
External services and supplies	6,930	6,927
Office and facilities	2,567	1,361
Depreciation and amortization.....	2,308	592
Insurance	1,658	1,207
Other	596	626
Total.....	\$ 37,176	\$ 38,225

Impairment of Long-lived assets

Impairment of long-lived assets relates mainly to the impairment of our leasehold improvements for the Alameda facility subleased to GeneFab as a result of our asset group reassessment which triggered a need to perform an impairment analysis following the closing of the GeneFab transaction.

Other Income (Expense)

Interest Income, net

Interest income, net consists of interest earned on our cash and cash equivalents, and short-term investments, if any, held during the year, net of interest expense.

Change in Fair Value of Contingent Earnout Liability

The change in fair value of the contingent earnout liability that was accounted for as a liability as of the date of the Merger is remeasured to fair value at each reporting period, resulting in a non-cash gain or loss.

Change in Fair Value of GeneFab Note Receivable - related party

The change in fair value of GeneFab Note Receivable consists of the remeasurement to fair value at each reporting period of the deferred consideration due from GeneFab for which we have elected the fair value option.

Change in Fair Value of GeneFab Economic Share - related party

The change in fair value of GeneFab Economic Share is a result of the change in the equity value of GeneFab at each reporting period.

Change in Fair Value of GeneFab Option - related party

The change in fair value of the GeneFab Option consists of the remeasurement to fair value at each reporting period of the derivative liability related to the option provided to GeneFab to acquire up to \$20.0 million in shares of our common stock at a purchase price of \$1.01867.

Gain on Extinguishment of Convertible Notes

Our convertible note was extinguished as part of the Merger and the change in fair value was recorded in earnings.

GeneFab sublease Income - related party

Other income (expense) is primarily comprised of income from our sublease with GeneFab.

Net Income (Loss) from Discontinued Operations

Net income (loss) from discontinued operations includes the results of our manufacturing and research activities related to the Alameda facility through the disposition date of August 7, 2023.

Net income (loss) from discontinued operations is summarized below (in thousands):

	Years Ended December 31,	
	2023	2022
Operating expenses:.....		
Research and development	\$ 10,003	\$ 5,922
General and administrative	(496)	2,623
Total operating expenses	9,507	8,545
Loss from discontinued operations	(9,507)	(8,545)
Other income (expense).....	(6)	—
Gain on disposal of business	21,861	—
Net income (loss) from discontinued operations	\$ 12,348	\$ (8,545)

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Years Ended December 31,		Change
	2023	2022	
Revenue			
Contract revenue	\$ 1,978	\$ 3,286	\$ (1,308)
Grant income	583	1,000	(417)
Total revenue.....	2,561	4,286	(1,725)
Operating expenses			
Research and development (included related party cost of \$3,113 and \$0, respectively).....	32,150	28,145	4,005
General and administrative	37,176	38,225	(1,049)
Impairment of long-lived assets	25,962	—	25,962
Total operating expenses	95,288	66,370	28,918
Loss from operations	(92,727)	(62,084)	(30,643)
Other income (expense)			
Interest income, net.....	2,864	1,701	1,163
Change in fair value of contingent earnout liability.....	207	9,461	(9,254)
Gain on extinguishment of convertible notes	—	1,289	(1,289)
Change in fair value of GeneFab Note Receivable - related party..	626	—	626
Change in fair value of GeneFab Economic Share - related party ..	16	—	16
Change in fair value of GeneFab Option - related party	3,318	—	3,318
GeneFab sublease income - related party	2,323	—	2,323
Other income (expense).....	(33)	(32)	(1)
Total other income (expense), net	9,321	12,419	(3,098)
Net loss from continuing operations.....	(83,406)	(49,665)	(33,741)
Net income (loss) from discontinued operations	\$ 12,348	\$ (8,545)	\$ 20,893
Net loss	\$ (71,058)	\$ (58,210)	\$ (33,741)

Contract revenue. For the years ended December 31, 2023 and 2022, we generated revenue from contracts and license agreements of \$2.0 million and \$3.3 million, respectively. The decrease of \$1.3 million was primarily due to decline in services provided under the Spark collaboration agreement.

Grant income. For the years ended December 31, 2023 and 2022, we generated revenue from grants of \$0.6 million and \$1.0 million, respectively. The decrease of \$0.4 million was primarily due to the recognition of revenue related to the SBIR SENTI-202 grant funding which was completed in FY 2023.

Research and development expenses. Research and development expenses were \$32.2 million and \$28.1 million for the years ended December 31, 2023 and 2022, respectively. The increase of \$4.0 million was primarily due to an increase of \$1.9 million in personnel-related expenses, which includes a \$0.8 million decrease in stock-based compensation expense, an increase of \$1.7 million in professional services costs and an increase of \$0.3 million in other research and development expenses.

General and administrative expenses. General and administrative expenses were \$37.2 million and \$38.2 million for the years ended December 31, 2023 and 2022, respectively. The decrease of \$1.0 million was primarily due to a decrease of \$4.4 million in personnel-related expenses, which includes a \$3.1 million decrease in stock-based compensation expense, partially offset by an increase of \$1.7 million in depreciation and amortization expenses, an increase of \$1.2 million in facility costs and an increase in insurance of \$0.5 million.

Impairment of long-lived assets. Impairment of long-lived assets was \$26.0 million for the year ended December 31, 2023, mainly due to the impairment of our leasehold improvements related to the Alameda facility subleased to GeneFab as a result of our asset group reassessment which triggered a need to perform an impairment analysis following the closing of the GeneFab transaction.

Interest Income, net. Interest income was \$2.9 million and \$1.7 million for the years ended December 31, 2023 and 2022, respectively. The increase of \$1.2 million was due to higher average cash balances, as well as an increase in interest rates in the relevant periods.

Change in fair value of contingent earnout liability. For the years ended December 31, 2023 and 2022, we recognized a non-cash gain of \$0.2 million and \$9.5 million, respectively. The decrease of \$9.3 million related to the decrease in the fair value of our common stock.

Gain on extinguishment of convertible notes. For the year ended December 31, 2022, we recognized a gain of \$1.3 million upon extinguishment of convertible notes.

Change in fair value of GeneFab Note Receivable - related party. For the year ended December 31, 2023, the change in fair value of GeneFab Note Receivable was a gain of \$0.6 million primarily due to a change in the discount rate and passage of time.

Change in fair value of GeneFab Option - related party. For the year ended December 31, 2023, the change in fair value of GeneFab Option was a gain of \$3.3 million primarily due to the decrease in the fair value of our common stock, which is a significant input in the measurement of the GeneFab Option.

GeneFab sublease income - related party. For the year ended December 31, 2023, sublease income was \$2.3 million from the sublease to GeneFab for the Alameda facility.

Net income (loss) from discontinued operations. Net income from discontinued operations was \$12.3 million for the year ended December 31, 2023, compared to net loss from discontinued operations of \$8.5 million for the year ended December 31, 2022. The increase was primarily due to the gain of \$21.9 million on the disposal of the assets sold to GeneFab and an increase of \$1.0 million in discontinued operations expense mainly stemming from increased personnel costs.

Liquidity and Capital Resources

Sources of Liquidity

From inception to December 31, 2023, we raised aggregate gross proceeds of \$300.1 million from the Merger and PIPE Financing, the issuance of shares of our common stock, the issuance of shares of our redeemable convertible preferred stock, the issuance of convertible notes, and to a lesser extent, through collaboration agreements and governmental grants.

On August 31, 2022, we entered into the Purchase Agreement with Chardan. Pursuant to the Purchase Agreement, we have the right, in our sole discretion, to sell to Chardan up to the lesser of: (i) \$50.0 million of shares of our common stock; and (ii) 8,727,049 shares of common stock at 97% of the volume weighted average price (“VWAP”) of the common stock calculated in accordance with the Purchase Agreement, over a period of 36 months subject to certain limitations and conditions contained in the Purchase Agreement. Sales and timing of any sales of common stock are solely at our election, and we are under no obligation to sell any securities to Chardan under the Purchase Agreement. As consideration for Chardan’s commitment to purchase shares of our common stock at our direction upon the terms and subject to the conditions set forth in the Purchase Agreement, upon execution of the Purchase Agreement, we issued 100,000 shares of our common stock to Chardan and paid a \$0.4 million document

preparation fee. We recognized an expense of \$0.7 million within general and administrative expenses in our consolidated statements of operations and comprehensive loss for the Chardan related costs and legal fees incurred in connection with the agreement.

Other than the issuance of the commitment shares of the Company’s common stock to Chardan, we issued 1,300,000 shares of Class A common stock through December 31, 2023, for aggregate net proceeds of \$1.2 million under the Common Stock Purchase Agreement. There were 1,000,000 issued during the year ended December 31, 2023 for aggregate net proceeds of \$0.5 million.

We do not have any products approved for sale and have not generated any revenue from product sales or otherwise. We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2023, we had \$35.9 million in cash, cash equivalents, and short-term investments, and an accumulated deficit of \$244.3 million, respectively.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, if at all. Should we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of our product candidates or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties rights to develop or commercialize our product candidates that we would prefer to retain.

The transaction with GeneFab, as described in “Recent Developments” above, provided us with additional capital in the form of a note receivable and rights to future manufacturing and research activities and reduced longer term operating expenses. In connection with the transaction, we are entitled to receive total consideration of \$37.8 million before the end of 2025, of which \$18.9 million was due at closing and was netted against prepayment owed by us for manufacturing and research activities to GeneFab. The remaining consideration of \$18.9 million will be received in installments during 2024 and 2025, subject to satisfaction of certain conditions. The Company determined that the \$18.9 million for future manufacturing and research activities, inclusive of the volume discount provided, was executed at market terms and does not result in any impact to the total consideration received from GeneFab for the disposal of the business.

Cash Flows

The following table sets forth a summary of our cash flows for each of the periods indicated (in thousands):

	Years Ended December 31,	
	2023	2022
Net cash from operating activities	\$ (52,395)	\$ (34,896)
Net cash from investing activities.....	30,077	(81,959)
Net cash from financing activities	779	118,551
Net change in cash and cash equivalents.....	<u>\$ (21,539)</u>	<u>\$ 1,696</u>

Operating Activities

For the year ended December 31, 2023, net cash used in operating activities of \$52.4 million was primarily due to our loss of \$71.1 million with non-cash expense adjustments of \$26.0 million for impairment of long-lived assets, \$9.7 million for stock-based compensation expense, and \$5.4 million for depreciation and amortization of operating lease right-of-use-assets offset by non-cash gains of \$21.9 million gain on disposal of business to GeneFab \$3.3 million gain from change in fair value of the GeneFab Option, \$1.1 million for accretion of discount on short-term investments, \$0.6 million gain for the change in fair value of the GeneFab receivable, and \$0.2 million gain for the change in fair value of contingent earnout liability. Other material changes were comprised of \$4.8 million decrease

in prepaid expenses and other current assets, \$0.7 million increase in sublease deferred income, \$0.5 million increase in operating lease liabilities and a \$0.4 million increase in accounts payable and accrued expenses and other liabilities, offset by \$0.9 million increase in accounts receivable and \$0.8 million decrease in deferred revenue.

For the year ended December 31, 2022, net cash used in operating activities of \$34.9 million was primarily due to our loss of \$58.2 million with non-cash adjustments of \$16.4 million for stock-based compensation expense, \$9.5 million for the change in fair value of the contingent earnout liability, \$3.9 million for depreciation and amortization of operating lease right-of-use-assets, \$1.3 million for gain on extinguishment of convertible notes and \$0.4 million for accretion of discount on short-term investments. Other material changes comprised of \$14.1 million increase in operating lease liabilities, \$2.2 million increase in accounts payable and accrued expenses and other current liabilities offset by \$1.3 million increase in prepaid expenses and other current assets and as well as a \$1.0 million decrease in deferred revenue.

Investing Activities

For the year ended December 31, 2023, net cash provided by investing activities of \$30.1 million was due to \$60.0 million in proceeds from maturities of short-term investments and \$0.1 million in proceeds from the sale of property and equipment, offset by \$18.0 million in purchases of short-term investments and \$12.0 million in purchases of property and equipment.

For the year ended December 31, 2022, net cash used in investing activities of \$82.0 million was due to \$40.6 million in purchases of short-term investments and \$41.4 million in purchases of property and equipment.

Financing Activities

For the year ended December 31, 2023, net cash provided by financing activities of \$0.8 million was primarily due to \$0.5 million from issuance of common stock under Common Stock Purchase Agreement and \$0.4 million from the issuance of common stock under Employee Stock Purchase Plan (ESPP), offset by \$0.1 million of principal finance lease payments.

For the year ended December 31, 2022, net cash provided by financing activities of \$118.6 million was primarily due to \$112.0 million proceeds received from Merger and related PIPE financing activities, net of transaction cost, \$5.2 million from issuance of convertible notes, \$0.7 million from issuance of common stock under Common Stock Purchase Agreement, \$0.5 million from the issuance of common stock upon exercise of stock options and \$0.2 million from the issuance of common stock under Employee Stock Purchase Plan (ESPP).

Funding Requirements

Based upon our current operating plans, we believe that our existing cash and cash equivalents will not be sufficient to fund our operations beyond the next twelve months from the date of this Annual Report. We anticipate that we will continue to seek additional funding, though the precise timing of such may prove uncertain. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our assumptions may prove to be inaccurate, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing and manufacturing product candidates in preclinical studies and clinical trials is costly and the timing and expenses in these trials are uncertain.

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

- the scope, rate of progress, results and costs of drug discovery, clinical and preclinical development, laboratory testing and clinical trials for our product candidates;
- the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of constructing and operating our planned cGMP facility and any commercial manufacturing activities;

- the cost associated with commercializing any approved product candidates;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights, defending intellectual property-related claims and obtaining licenses to third-party intellectual property;
- the timing and amount of any milestone and royalty payments we are required to make under our present or future license agreements;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies and associated intellectual property.

In order to improve our liquidity, management is actively pursuing additional financing. We will need to obtain substantial additional funding for continuing operations. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce or eliminate our research or drug development programs or any future commercialization efforts. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

Accounting standards require that management evaluate whether we have adequate financial resources to continue as a going concern beyond twelve months after the date that these consolidated financial statements are available to be issued. Management has determined that additional funds will be needed to continue as a going concern for the period defined in the accounting standards.

Contractual Obligations and Commitments

On June 3, 2021, we entered into a lease agreement for a new cGMP facility in Alameda, California to support planned initial clinical trials for our product candidates. The lease will expire in 2032 with future undiscounted operating lease payments of \$46.0 million over an initial lease period of eleven years. See Note 7 - *Operating Leases* for details on our lease obligations.

During the year ended December 31, 2021, we entered into a three-year collaboration and option agreement with BlueRock Therapeutics LP (“BlueRock”) under which the Company granted BlueRock an option to execute an exclusive or non-exclusive license to develop, manufacture and commercialize cell therapy products (See Part II, Item 8, Notes to Consolidated Financial Statements, Note 16 - *Related Parties* for details into the BlueRock agreement). In consideration for the option, the Company is responsible for up to \$10.0 million in research and development costs and expenses associated with the collaboration plan incurred over the three-year term.

We have also entered into license agreements under which we are obligated to make annual maintenance payments of \$0.2 million and specified milestone and royalty payments. Milestone and royalty payment obligations under these agreements are contingent upon future events, such as our achievement of specified development, regulatory, and sales milestones, or generating product sales. As of December 31, 2023, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Following the closing of the Merger, former holders of Legacy Senti common stock and preferred stock may receive up to 2,000,000 additional shares of the Company’s common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche. Refer to Note 9, *Stockholders’ Equity (Deficit)*, for further details of the contingent earnout.

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Critical Accounting Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting

principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates and assumptions on historical experience, known trends and events, and various other factors that are believed to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies and estimates to be most critical to the preparation of our consolidated financial statements. We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are inherently uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

Impairment of Long-Lived Assets

As a result of the change in the manner in which the Company expects to recover the assets associated with the lease on the Alameda facility to GeneFab and the related leasehold improvements became a separate asset group for the purposes of long-lived asset impairment assessment. This asset group reassessment triggered a need to perform an impairment analysis. The Company tested the asset group for impairment and recognized an impairment loss in the amount of \$25.7 million during the year ended December 31, 2023, representing the difference between the carrying value of the asset group of \$54.6 million and its estimated fair value of \$28.9 million, determined based on the discounted cash flows expected to be generated from the use of the asset group through the sublease. Further, the Company determined that the individual fair value of the ROU asset within the asset group exceeded its carrying value as of the impairment testing date. Accordingly, the Company allocated the entire impairment loss to the leasehold improvements associated with the Alameda lease.

GeneFab Note Receivable

We elected to account for the GeneFab Note Receivable from GeneFab under the fair value option in ASC 825, *Financial Instruments* (“ASC 825”). The GeneFab Note Receivable was recorded at its fair value on issuance and subsequently remeasured each reporting period with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss until settlement. We estimated the fair value by discounting future payments under multiple probability-weighted scenarios using GeneFab’s cost of borrowing based on published CCC-rated corporate bond yields.

GeneFab Economic Share

We elected to account for the GeneFab Economic Share under the fair value option in ASC 825. The GeneFab Economic Share was recorded at its fair value on issuance and subsequently remeasured each reporting period with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss until settlement. We estimated the fair value using the option pricing method, which allocates total estimated enterprise value to various classes of equity using the Backsolve method. Significant assumptions used were the equity value of GeneFab, volatility, risk-free rate, expected term, and dividend yield.

GeneFab Option

The GeneFab Option meets the definition of a derivative under ASC 815, *Derivatives and Hedging* (“ASC 815”), and does not meet the criteria for equity classification. The derivative liability was recorded at its fair value on issuance and subsequently remeasured each reporting period with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss until settlement. The fair value of the liability was determined using a Black-Scholes option pricing model incorporating assumptions such as the fair value of our common stock, the risk-free rate, volatility, expected term and dividend yield.

Contingent Earnout Liability

In connection with the Reverse Recapitalization, Legacy Senti equity holders are entitled to receive as additional merger consideration up to 2,000,000 shares of our common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche, for no consideration upon the occurrence of certain triggering events, including a change of control event. In accordance with ASC 815, as certain terms of the Contingent Earnout Shares were not indexed to the common stock, they were accounted for as a liability at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

The estimated fair value of the Contingent Earnout Shares was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including our current common stock price, expected volatility, risk-free rate, expected term and expected dividend yield.

The common stock price was based on the closing price of our common stock as reported on the date at the Reverse Recapitalization and each reporting date. Historically, we have been a private company and lacked company-specific and implied volatility information for our common stock. Therefore, we estimated our expected volatility based on the historical volatility of a representative group of public companies in the biotechnology industry for the expected terms. The risk-free rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the expected term of the Contingent Earnout Shares. The expected dividend yield was 0% based on the fact that we have never paid or declared dividends. The risk-free rate and expected volatility requires significant judgment and actual results can differ from assumed and estimated amounts.

Our board of directors and management develop best estimates based on the application of these approaches and the assumptions underlying these valuations, giving careful consideration to the advice from our third-party valuation expert. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation expense could be materially different.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act (“JOBS”) Act permits an emerging growth company to take advantage of an extended transition to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company is an “emerging growth company” as defined in Section 2(a) of the Securities Act, and has elected to not take advantage of the benefits of this extended transition period.

We expect to remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of the Dynamics Initial Public Offering (“IPO”) (which occurred on May 25, 2021), (b) in which we have total annual revenue of at least \$1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds \$700 million as of the end of that fiscal year’s second fiscal quarter and our net sales for the year exceed \$100 million; and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the preceding, rolling three-year period.

Smaller Reporting Company Status

The Company is a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company if (1) the market value of our common stock held by non-affiliates is less than \$250 million as of the last business day of the second fiscal quarter, or (2) our annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter are less than \$100 million and the market value of our common stock held by non-affiliates is less than \$700 million as of the last business day of the second fiscal quarter.

Segment Information

We have one business activity and operate in one reportable segment.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We qualify as a smaller reporting company, as defined by Item 10 of Regulation S-K and, thus, are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data

**SENTI BIOSCIENCES, INC.
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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Senti Biosciences, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Senti Biosciences, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations, and has an accumulated deficit 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.

Emphasis of Matter

As discussed in Note 4 and 16 to the consolidated financial statements, the Company entered into a significant related party transaction with GeneFab, LLC that met the criteria to be reported as discontinued operations. Our opinion with respect to this matter is not modified.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. 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/ KPMG LLP

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

San Francisco, California
March 21, 2024

SENTI BIOSCIENCES, INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2023	2022
Assets		
Cash and cash equivalents	\$ 35,926	\$ 57,621
Accounts receivable	112	626
GeneFab receivable - related party	17,592	—
Short-term investments.....	—	40,942
GeneFab prepaid expenses - related party	14,787	—
Prepaid expenses and other current assets	2,783	3,181
Current assets of discontinued operations	—	209
Total current assets.....	71,200	102,579
Restricted cash.....	3,522	3,366
GeneFab receivable - related party, net of current portion	1,119	—
Property and equipment, net.....	25,338	51,361
Operating lease right-of-use assets.....	16,274	18,418
GeneFab Economic Share - related party	1,816	—
Other long-term assets.....	215	283
Noncurrent assets of discontinued operations	—	4,785
Total assets.....	\$ 119,484	\$ 180,792
Liabilities and Stockholders' Equity		
Accounts payable	\$ 1,250	\$ 1,370
Finance lease liabilities - related party, current portion.....	97	—
Early exercise liability, current portion	135	135
Deferred revenue	—	799
GeneFab sublease deferred income - related party	989	—
Accrued expenses and other current liabilities	5,927	12,576
Operating lease liabilities	4,031	1,988
Current liabilities of discontinued operations.....	243	1,185
Total current liabilities	12,672	18,053
Operating lease liabilities, net of current portion	33,538	35,103
Contingent earnout liability	20	227
GeneFab Option - related party	6,331	—
Early exercise liability, net of current portion	10	146
Total liabilities	52,571	53,529
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 500,000,000 shares authorized at December 31, 2023 and December 31, 2022; 45,700,161 and 44,062,534 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively.....	5	4
Additional paid-in capital	311,252	300,544
Accumulated other comprehensive income.....	—	1
Accumulated deficit	(244,344)	(173,286)
Total stockholders' equity	66,913	127,263

Total liabilities, redeemable convertible preferred stock and stockholders' equity... \$ 119,484 \$ 180,792

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

SENTI BIOSCIENCES, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Years Ended December 31,	
	2023	2022
Revenue		
Contract revenue	\$ 1,978	\$ 3,286
Grant income.....	583	1,000
Total revenue.....	2,561	4,286
Operating expenses		
Research and development (included related party cost of \$3,113 and \$—, respectively).....	32,150	28,145
General and administrative	37,176	38,225
Impairment of long-lived assets	25,962	—
Total operating expenses.....	95,288	66,370
Loss from operations	(92,727)	(62,084)
Other income (expense)		
Interest income, net.....	2,864	1,701
Change in fair value of contingent earnout liability.....	207	9,461
Change in fair value of GeneFab Note Receivable - related party	626	—
Change in fair value of GeneFab Economic Share - related party	16	—
Change in fair value of GeneFab Option - related party	3,318	—
Gain on extinguishment of convertible notes.....	—	1,289
GeneFab sublease income - related party.....	2,323	—
Other income (expense)	(33)	(32)
Total other income (expense), net.....	9,321	12,419
Net loss from continuing operations.....	(83,406)	(49,665)
Net income (loss) from discontinued operations	12,348	(8,545)
Net loss.....	(71,058)	(58,210)
Other comprehensive gain (loss)		
Unrealized gain (loss) on investments	(1)	1
Comprehensive loss.....	\$ (71,059)	\$ (58,209)
Net loss per share, basic and diluted		
Net loss per share from continuing operations, basic and diluted.....	\$ (1.88)	\$ (1.90)
Net income (loss) per share from discontinued operations, basic and diluted.....	\$ 0.28	\$ (0.33)
Net loss per share, basic and diluted.....	\$ (1.60)	\$ (2.23)
Weighted-average shares outstanding, basic and diluted.....	44,372,223	26,110,785

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

SENTI BIOSCIENCES, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)	
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	19,517,988	\$ 171,833	2,972,409	\$ —	\$ 3,619	0	\$ (115,076)	\$ (111,457)
Conversion of redeemable convertible preferred stock into common stock in connection with the Reverse Recapitalization, net of transaction cost	(19,517,988)	(171,833)	19,517,988	2	171,833	—	—	171,835
Issuance of common stock upon Reverse Recapitalization, net of transaction costs	—	—	19,975,963	2	111,957	—	—	111,959
Contingent earnout liability recognized upon closing of the Reverse Recapitalization	—	—	—	—	(9,688)	—	—	(9,688)
Cancellation and exchange of convertible note in connection with PIPE financing	—	—	517,500	—	5,184	—	—	5,184
Gain recognized on fair value of embedded derivative on SPAC merger date	—	—	—	—	(1,289)	—	—	(1,289)
Common Stock Purchase Agreement settled in common stock, net of fees	—	—	400,000	—	924	—	—	924
Exercise of common stock options	—	—	199,839	—	496	—	—	496
Vesting of early exercise of common stock options	—	—	367,878	—	965	—	—	965
Issuance of common stock under Employee Stock Purchase Plan (ESPP)	—	—	110,957	—	151	—	—	151
Stock-based compensation expense	—	—	—	—	16,392	—	—	16,392
Unrealized gain (loss) on investments	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(58,210)	(58,210)
Balance as of December 31, 2022	—	\$ —	44,062,534	\$ 4	\$ 300,544	\$ 1	\$ (173,286)	\$ 127,263
Common Stock Purchase Agreement settled in common stock, net of fees	—	—	1,000,000	1	527	—	—	528
Vesting of early exercise of common stock options	—	—	50,640	—	136	—	—	136
Issuance of common stock under Employee Stock Purchase Plan (ESPP)	—	—	586,987	—	375	—	—	375
Stock-based compensation expense	—	—	—	—	9,670	—	—	9,670
Unrealized gain (loss) on investments	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(71,058)	(71,058)

Balance as of December 31, 2023	—	\$	—	45,700,161	\$	5	\$	311,252	\$	—	\$	(244,344)	\$	66,913
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The accompanying notes are an integral part of these consolidated financial statements.

SENTI BIOSCIENCES, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (71,058)	\$ (58,210)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3,561	1,398
Amortization of operating lease right-of-use assets	1,868	2,522
Accretion of discount on short-term investments	(1,069)	(356)
Gain on extinguishment of convertible notes	—	(1,289)
Gain on disposal of business	(21,862)	—
Change in fair value of contingent earnout liability	(207)	(9,461)
Change in fair value of GeneFab Note Receivable - related party	(626)	—
Change in fair value of GeneFab Economic Share - related party	(16)	—
Change in fair value of GeneFab Option - related party	(3,318)	—
Impairment of long-lived assets	25,962	—
Stock-based compensation expense	9,670	16,392
Issuance of common stock for Common Stock Purchase Agreement fee	—	196
Other non-cash charges	35	8
Changes in assets and liabilities:		
Accounts receivable	507	(131)
GeneFab receivable - related party	(1,436)	—
GeneFab prepaid expenses - related party	4,113	—
Prepaid expenses and other assets	681	(1,302)
Accounts payable	(290)	186
Accrued expenses and other current liabilities	716	2,055
GeneFab sublease deferred income - related party	689	—
Deferred revenue	(799)	(1,033)
Operating lease liabilities	484	14,129
Net cash from operating activities	(52,395)	(34,896)
Cash flows from investing activities		
Purchases of short-term investments	(17,990)	(40,585)
Maturity of short-term investments	60,000	—
Purchases of property and equipment	(12,038)	(41,374)
Proceeds from sale of property and equipment	105	—
Net cash from investing activities	30,077	(81,959)
Cash flows from financing activities		
Proceeds from Merger and related PIPE financing, net of transaction costs	—	111,976
Proceeds from issuance of common stock upon exercise of stock options	—	521
Proceeds from issuance of common stock under Common Stock Purchase Agreement	512	728
Proceeds from issuance of common stock under Employee Stock Purchase Plan (ESPP)	375	151
Proceeds from issuance of convertible notes	—	5,175

	Years Ended December 31,	
	2023	2022
Principal finance lease payments.....	(108)	—
Net cash from financing activities	779	118,551
Net (decrease) increase in cash and cash equivalents.....	(21,539)	1,696
Cash, cash equivalents, and restricted cash, beginning of period.....	60,987	59,291
Cash, cash equivalents, and restricted cash, end of period	39,448	60,987

Reconciliation of cash, cash equivalents and restricted cash

Cash and cash equivalents.....	\$ 35,926	\$ 57,621
Restricted cash	3,522	3,366
Total cash, cash equivalents and restricted cash.....	\$ 39,448	\$ 60,987

Supplemental disclosures of noncash financing and investing items

Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities.....	\$ 15	\$ 8,153
Refer to Note 4. <i>GeneFab Transaction</i> for details of non-cash items		

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

Notes to Consolidated Financial Statements

1. Organization and Description of Business

Senti Biosciences, Inc. and its subsidiaries (the “Company” or “Senti”), is an early clinical stage biotechnology company developing next-generation cell and gene therapies engineered with its gene circuit platform technologies for patients living with incurable diseases. Senti’s mission is to create a new generation of smarter therapies that can outsmart complex diseases using novel and unprecedented approaches. Senti has built a synthetic biology platform that enables it to program next-generation cell and gene therapies with gene circuits. These gene circuits, which are created from novel and proprietary combinations of DNA sequences, reprogram cells with biological logic to sense inputs, compute decisions and respond to their cellular environments. The Company is headquartered in South San Francisco, California.

On June 8, 2022 (the “Closing Date”), Dynamics Special Purpose Acquisition Corp. (“Dynamics” or “DYNS”) consummated a merger pursuant to which Explore Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and wholly owned subsidiary of Dynamics, merged with and into Senti Sub I, Inc., formerly named Senti Biosciences, Inc. (“Legacy Senti”), with Legacy Senti surviving as a wholly-owned subsidiary of Dynamics (such transactions, the “Merger,” and, collectively with the other transactions described in the merger agreement (as defined below, the “Reverse Recapitalization”). As a result of the Merger, Dynamics was renamed Senti Biosciences, Inc.

Refer to Note 3. *Reverse Recapitalization*, for further details of the Merger.

On August 7, 2023, the Company completed a transaction with GeneFab, LLC (“GeneFab”), a contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. As part of that transaction, the Company disposed of its non-oncology business and in-house manufacturing services and subleased its manufacturing facility to GeneFab.

Refer to Note 4. *GeneFab Transaction*, for further details of the transaction, and to Note 16. *Related Parties*, for related party discussion.

Liquidity and Going Concern

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

The Company has devoted substantially all of its efforts to organizing and staffing, business planning, raising capital, and conducting preclinical studies and has not realized substantial revenues from its planned principal operations. To date, the Company raised aggregate gross proceeds of \$300.1 million from the Merger and PIPE Financing, the issuance of shares of our common stock, the issuance of shares of our redeemable convertible preferred stock, the issuance of convertible notes and, to a lesser extent, through collaboration agreements and governmental grants.

At December 31, 2023 and December 31, 2022, the Company had an accumulated deficit of \$244.3 million and \$173.3 million, respectively. The Company’s net losses were \$71.1 million and \$58.2 million for the years ended December 31, 2023 and 2022, respectively. Substantially all of the Company’s net losses resulted from costs incurred in connection with the Company’s research and development programs, from general and administrative costs associated with the Company’s operations, and impairment of the Company’s long-lived assets. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future as the Company advances its preclinical activities and clinical trials for its product candidates in development.

As of December 31, 2023 and 2022, the Company had cash, cash equivalents, and short-term investments of \$35.9 million and \$98.6 million. As of March 21, 2024, the issuance date of the consolidated financial statements as

Notes to Consolidated Financial Statements

of and for the year ended December 31, 2023, there is uncertainty about whether the Company's combined cash, cash equivalents, and short-term investments will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements, beyond twelve months from the issuance date of these financial statements and therefore the Company concluded that substantial doubt existed about the Company's ability to continue as a going concern.

The transaction with GeneFab provided the Company with additional capital in the form of a note receivable and rights to future manufacturing and research activities and reduced longer-term operating expenses. Refer to Note 4. *GeneFab Transaction*, for further details of the GeneFab transaction.

The Company's continued existence is dependent upon management's ability to raise capital and develop profitable operations. Management is devoting substantially all of its efforts to developing its business and raising capital and there can be no assurance that the Company's efforts will be successful. No assurance can be given that management's actions will result in profitable operations or the meeting of ongoing liquidity needs.

NASDAQ Bid Price Compliance Notice

On August 7, 2023, the Company received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Listing Qualifications Department") notifying the Company that, for the last 30 consecutive trading days, the closing bid price of the Company's common stock had closed below the minimum bid price requirement of \$1.00 per share for continued listing on The Nasdaq Global Market. The Company had been provided an initial compliance period of 180 calendar days, or until February 5, 2024, to regain compliance with the minimum bid price requirement. Issuers listed on The Nasdaq Global Market are not eligible for a second 180-day grace period under the Nasdaq Listing Rules. However, based upon the Company's compliance with the various criteria required under Nasdaq Listing Rule 5810(c)(3)(A)(ii) to obtain a second 180-day grace period applicable to issuers listed on The Nasdaq Capital Market, the Company applied to transfer the listing of its Common Stock to The Nasdaq Capital Market.

Refer to Note 17. *Subsequent Events*, for additional information on NASDAQ bid price compliance.

2. Summary of Significant Accounting Policies***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of Senti Biosciences, Inc., and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company has one business activity and operates in one reportable segment within continuing operations.

Unless otherwise noted, the Company has retroactively adjusted all common and preferred share and related price information to give effect to the exchange ratio established in the Merger Agreement.

The Company determined that the assets sold to GeneFab met the criteria for presentation as a discontinued operation. As a result, the Company has retrospectively restated its consolidated balance sheet at December 31, 2022 and consolidated statements of operations and comprehensive loss for the year ended December 31, 2022 to reflect the assets and liabilities and operating results, respectively, related to the disposed business in discontinued operations. The Company has chosen not to segregate the cash flows of the disposed business in the consolidated statements of cash flows. Supplemental disclosures related to discontinued operations for the statements of cash flows have been provided in Note 4. *GeneFab Transaction*. Unless otherwise specified, the disclosures in these consolidated financial statements refer to continuing operations only.

Notes to Consolidated Financial Statements

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 and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the valuation of stock-based awards, the accrual for research and development expenses, the valuation of contingent earnout, the valuation of GeneFab Option, the valuation of GeneFab Economic Share, the valuation of the GeneFab Note Receivable, the discount rate used to discount future cash flows for the impairment of long-lived assets, and the determination of the incremental borrowing rate. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash, cash equivalents, and short-term investments that are maintained in checking and money market accounts at one financial institution, which at times, may exceed federally insured limits. The Company’s short-term investments, if any, are limited to certain types of debt securities issued by the U.S. government, its agencies, and institutions with investment-grade credit ratings, and places restrictions on maturities and concentration by type and issuer. As of December 31, 2023 and 2022, the Company has not experienced any credit losses in such accounts or investments.

As of December 31, 2023, the Company has prepaid future manufacturing and research services of \$14.8 million under the development and manufacturing services agreement entered into with GeneFab, a related party. The Company also has a receivable from GeneFab under the framework agreement with a fair value of \$17.2 million, subject to satisfaction of certain conditions. The prepaid expense and receivable balances from GeneFab potentially subject the Company to a significant concentration of credit risk if the Company is unable to realize these balances. Refer to Note 4. *GeneFab Transaction*, for further details of the GeneFab transaction.

Cash, Cash Equivalents, and Restricted Cash

Cash equivalents consist of amounts deposited in money market funds and securities with original maturity dates of three months or less, which are stated at fair value.

The Company’s restricted cash consists of cash deposited with a financial institution as collateral for a letter of credit required under the Company’s headquarters and research facility leases as well as employee contributions collected under employee stock purchase plan. The restricted cash is presented separately from cash and cash equivalents and classified as non-current on the consolidated balance sheets, as the Company expects the cash to remain restricted for a period greater than one year.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets that total to the amounts shown in the consolidated statements of cash flows for the Company:

	December 31,	
	2023	2022
Cash and cash equivalents	\$ 35,926	\$ 57,621
Restricted cash.....	3,522	3,366
Total	<u>\$ 39,448</u>	<u>\$ 60,987</u>

Short-term Investments

Investments in marketable securities with original maturities less than 12 months from the balance sheet date, if any, are classified as short-term investments. Investments with original maturities of greater than 12 months from

Notes to Consolidated Financial Statements

the balance sheet date, if any, are classified as long-term. The Company classifies all of its investments as available-for-sale and records such assets at estimated fair value in the consolidated balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive loss within the consolidated statement of operations and comprehensive loss, and as a separate component of stockholders' equity. These investments consist of corporate debt securities, U.S. Government securities, asset-based securities, and commercial paper, which are subject to minimal credit and market risk. Unrealized gains and losses are included in other comprehensive loss. Interest on available-for-sale securities is included in interest income in the consolidated statements of operations and comprehensive loss.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or the exit price that would be paid to transfer a liability 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. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- 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 that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The estimated fair values of the Company's cash and cash equivalents, restricted cash, trade, and other receivables and accounts payable approximate their carrying values given their short-term nature.

Fair Value Option

The Company elected to account for the deferred consideration (GeneFab Note Receivable) and contingent consideration receivable (GeneFab Economic Share) from the GeneFab transaction under the fair value option in ASC 825, *Financial Instruments* ("ASC 825"). Accordingly, these instruments were recognized at their fair value at the closing of the transaction and are subsequently remeasured each reporting period with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss until settlement. The fair value of the GeneFab Note Receivable was determined by discounting future payments under multiple probability-weighted scenarios using GeneFab's cost of borrowing. The fair value of the GeneFab Option was determined using an option pricing method. Refer to Note 4. *GeneFab Transaction*, for further details of the GeneFab transaction.

Notes to Consolidated Financial Statements

Property and Equipment, Net

Property and equipment, net is stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which are as follows:

Asset Classification	Estimated useful Life
Small equipment.....	2 years
Computer equipment and software	3 years
Laboratory equipment.....	5-7 years
Furniture and fixtures	5-7 years
Leasehold improvements.....	Shorter of the lease term and the useful life

The Company capitalizes certain costs incurred during the construction phase of a project or asset into construction-in-progress. Once the construction is complete and the asset is placed into service, the Company transfers its carrying value into the appropriate fixed asset category and begins depreciating the value over its useful life.

When assets are retired or disposed of, any resulting gain or loss is included in net loss. Expenditures for maintenance and repairs are expensed as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, such as property and equipment, net and lease ROU assets, for impairment whenever events or changes in circumstances indicate that the carrying value of assets may not be recoverable. Recoverability of these assets is measured by comparing their carrying value to the future net undiscounted cash flows the assets are expected to generate over their remaining economic life. If such assets are considered to be impaired, the amount of any impairment is measured as the difference between their carrying value and their fair value. If the useful life is shorter than originally estimated, the Company amortizes the remaining carrying value over the revised shorter useful life.

Leases

The Company determines if an arrangement is or contains a lease at inception. Operating leases are recorded on the consolidated balance sheets with right-of-use assets (“ROU”) representing the Company’s right to use an underlying asset for the lease term and lease liabilities representing the Company’s obligation to make lease payments. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Operating lease ROU assets also include the effect of any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. As the implicit rate in the Company’s leases is typically unknown, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The Company gives consideration to its credit risk, the term of the lease, and total lease payments and adjusts for the impacts of collateral as necessary when calculating its incremental borrowing rates. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. Variable lease payments are recorded as an expense in the period incurred.

The Company has elected to not separate lease and non-lease components for any leases within its existing classes of assets and, as a result, accounts for any lease and non-lease components as a single lease component. The Company has also elected not to apply the recognition requirement for leases with a term of 12 months or less.

Revenue Recognition

Contract Revenue

Revenue is recognized when a customer obtains control of promised goods or services. The Company applies the following five steps to recognize revenue: (i) identify the contract with a customer; (ii) identify the performance

Notes to Consolidated Financial Statements

obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligations are satisfied.

A performance obligation is defined as a promise to transfer a product or a service to a customer that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not distinct from other promises in the contract, such promises should be combined into a single performance obligation. The assessment of each of these elements may require significant judgments.

Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. If these options provide a material right to the customer, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. The Company's agreements may include both fixed and variable consideration. Fixed payments are included in the transaction price, while variable consideration, such as milestone payments and fees for research services, are estimated and constrained (if required) at the inception of the contract and evaluated on a periodic basis thereafter.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation based on the relative stand-alone selling price ("SSP") of the performance obligation. The Company determines SSP at contract inception and at contract modification. Determining the SSP for performance obligations requires significant judgment. Changes in the key assumptions used to determine the SSP could have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

For each distinct performance obligation, revenue is recognized as the Company transfers control of the product or the service applicable to such performance obligations. In instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until the Company satisfies such performance obligations. In instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is a contract asset recorded in prepaid expenses and other current assets on the consolidated balance sheets.

Grant Income

The Company receives government grants that reimburses the Company for certain allowable costs for funded projects. Grant income is recognized on a systematic basis over the period in which the Company recognizes qualified research and development costs that grant is intended to compensate and there is reasonable assurance that the Company will meet the terms and conditions of the grant. This income is recorded as grant income in the consolidated statements of operations and comprehensive loss.

Grant payments received in excess of grant revenue earned are recognized as deferred revenue on the balance sheets, and grant income earned in excess of grant payments received is recognized as trade and other receivables on the consolidated balance sheets.

Research and Development

Research and development costs are expensed as incurred. Research and development costs consist of salaries and other personnel-related expenses, including associated stock-based compensation expense, lab supplies and services, in-license and technology costs, consulting and sponsored research fees, manufacturing costs, facility costs and depreciation expense.

Notes to Consolidated Financial Statements

Nonrefundable advance payments for goods and services that will be used or received in future research and development activities are deferred and recognized as an expense in the period in which the related goods are delivered, or services are performed. Similarly, GeneFab prepaid expenses are recognized as an expense in the period in which the related manufacturing or research activities are performed.

The Company has acquired and may continue to acquire the rights to gene circuit or other technologies from third parties. The upfront payments to acquire a license, product, or rights, as well as any annual maintenance charges and future milestone payments, are immediately recognized as research and development expense provided that there is no alternative future use of the rights in other research and development projects.

GeneFab Option

The option granted to GeneFab as part of the GeneFab transaction meets the definition of a derivative under ASC 815, *Derivatives and Hedging* (“ASC 815”), and does not meet the criteria for equity classification. The derivative liability is recorded at its fair value on issuance and subsequently remeasured each reporting period with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss until settlement. The fair value of the derivative liability was determined using a Black-Scholes option pricing model.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has occurred and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount, the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of December 31, 2023 and 2022.

Contingent Earnout Equity

In connection with the Reverse Recapitalization and pursuant to the Merger dated as of June 8, 2022 by and among the Merger Sub and Legacy Senti, former holder of the Legacy Senti common stock and Legacy Senti preferred stock are entitled to receive as additional consideration of up to 2,000,000 shares of the Company’s Common Stock (the “Contingent Earnout Shares”), comprised of two separate tranches of 1,000,000 shares per tranche, for no consideration upon the achievement of certain share price milestones within a period of two and three years. The Contingent Earnout Shares are a form of dividend for holders of Legacy Senti common stock and Legacy Senti preferred stock. If there is a change of control within the three-year period following the closing of the Merger that results in a per share price equal to or in excess of certain share price milestones not previously met, then the Company shall issue the earnout shares to the holders of Legacy Senti common stock and preferred stock. In accordance with ASC 815 as certain terms of the contingent earnout shares were not indexed to the common stock, equity treatment is precluded and liability classification is required at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value recorded as Change in fair value of contingent earnout liability in the consolidated statements of operations and comprehensive loss. A portion of the earnout shares were granted to holders of Legacy Senti common stock that are subject to repurchase, and as of the date of the Merger were accounted for as stock-based compensation expense and expensed as there was no remaining service period.

The estimated fair value of the Contingent Earnout Shares was determined using a Monte Carlo simulation using a distribution of potential outcomes on a monthly basis over a three-year period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including the current Company common stock price, expected volatility, risk-free rate, expected term and expected dividend yield.

Stock-Based Compensation Expense

The Company recognizes stock-based compensation expense related to employees and non-employees based on the grant date fair value of the awards. For awards that vest solely based on continued service, stock-based

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compensation expense is recognized in the consolidated statements of operations and comprehensive loss using the straight-line method. For performance and market awards, stock-based compensation expense is recognized over the requisite service period using the accelerated attribution method. No compensation expense will be recognized for awards subject to performance conditions until it is probable that the performance condition will be met.

The Company recognizes stock-based compensation expense related to purchase rights issued pursuant to its employee stock purchase plan on a straight-line basis over the offering period.

The Company has allowed specified option holders to exercise unvested options. The options that are exercised prior to vesting continue to vest according to the respective option agreement, and such unvested shares are subject to repurchase by the Company at the option holder's original exercise price in the event the option holder's service with the Company voluntarily or involuntarily terminates.

The Company records proceeds from the early exercise of options as a current and long-term liability in the consolidated balance sheets, and reclassifies this liability to additional paid-in capital as the Company's repurchase right lapses. The shares purchased by the option holders pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares have vested.

Net Loss Per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net 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 loss available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in undistributed earnings as if all loss for the period had been distributed.

Basic earnings per share for both continuing and discontinued operations is computed by dividing net loss from continuing operations and net income (loss) from discontinued operations attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings per share for both continuing and discontinued operations is computed by adjusting net earnings for both continuing and discontinued operations for an allocation of the undistributed earnings and dividing it by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, the Company's outstanding stock options, redeemable convertible preferred stock, and potential issuance of redeemable convertible preferred stock under existing preferred stock tranches, are considered potential dilutive common shares.

The Company's participating securities contractually entitle the holders of such securities to participate in dividends but do not contractually require the holders of such securities to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. When the Company is reporting discontinued operations, it uses net loss from continuing operations as the control number in determining whether those potential dilutive securities are dilutive or anti-dilutive.

Income Taxes

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

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

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. To date, there have been no interest charges or penalties related to unrecognized tax benefits.

Recently Adopted Accounting Standards

In November 2021, the FASB issued Accounting Standards Update (ASU) No. 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which requires business entities to provide certain disclosures when they have received government assistance and use a grant or contribution accounting model by analogy to other accounting guidance. The ASU was effective January 1, 2022, and had no material impact on the Company's consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04 Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 370-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40); Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force), which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The ASU was effective January 1, 2022, and had no material impact on the Company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The ASU was effective January 1, 2022, and had no material impact on the Company's consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740), which removes certain exceptions to the general principles in Topic 740 and improves consistent application of and simplifies GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The ASU was effective January 1, 2022, and had no material impact on the Company's consolidated financial statements and related disclosures.

Recent Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires an enhanced disclosure of significant segment expenses on an annual and interim basis. This guidance is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Upon adoption, the guidance should be applied retrospectively to all prior periods presented in the financial statements.

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In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which improves income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. Upon adoption, the guidance can be applied prospectively or retrospectively.

The Company believes that the impact of recently issued accounting standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

3. Reverse Recapitalization

On June 8, 2022, Merger Sub, a wholly-owned subsidiary of Dynamics, merged with Legacy Senti, with Legacy Senti surviving as a wholly-owned subsidiary of Dynamics. At the effective time of the Merger:

- each outstanding share of Legacy Senti common stock was converted into approximately 0.1957 shares of the Company's common stock;
- each outstanding share of preferred stock of Legacy Senti was cancelled and converted into the aggregate number of shares of the Company's common stock that would be issued upon conversion of the shares of Legacy Senti preferred stock based on the applicable conversion ratio immediately prior to the effective time, multiplied by approximately 0.1957;
- each outstanding option to purchase Legacy Senti common stock was converted into an option to purchase a number of shares of the Company's common stock equal to the number of shares of Legacy Senti common stock subject to such option multiplied by approximately 0.1957, rounded down to the nearest whole share, at an exercise price per share equal to the current exercise price per share for such option divided by approximately 0.1957, rounded up to the nearest whole cent; and
- all shares of Dynamics Class A common stock were redesignated as common stock, par value \$0.0001 per share, of the Company.

Former holders of the Legacy Senti common stock and preferred stock are eligible to receive up to an aggregate of 2,000,000 additional shares of the Company's common stock in the aggregate in two equal tranches of 1,000,000 shares if the volume-weighted average closing sale price of the common stock is greater than or equal to \$15.00 and \$20.00, respectively, for any 20 trading days within any 30 consecutive trading day period. The first and second tranche term is two and three years, respectively, from the closing of the Merger. If there is a change of control within the three-year period following the closing of the Merger that results in a per share price equal to or in excess of the \$15.00 and \$20.00 share price milestones not previously met, then the Company shall issue the earnout shares to the holders of Legacy Senti common stock and preferred stock. Refer to Note 9, *Stockholders' Equity (Deficit)*, for further details of the contingent earnout liability.

In association with the Merger, Dynamics entered into subscription agreements (the "Subscription Agreements") with certain investors (the "PIPE Investors"). Pursuant to the Subscription Agreements, the PIPE Investors purchased an aggregate of 5,060,000 shares of the Company's common stock (the "PIPE Shares") in a private placement at a price of \$10.00 per share for an aggregate purchase price of \$50.6 million (the "PIPE Financing"). The PIPE Financing was consummated in connection with the Merger.

Concurrently with the closing of the Merger, the unsecured convertible promissory note (the "May 2022 Note") in the principal amount of \$5.2 million that was previously issued by Legacy Senti to Bayer Healthcare LLC ("Bayer") on May 19, 2022 was automatically cancelled and exchanged for 517,500 shares of Class A Common Stock (the "Note Exchange") at a price of \$10.00 per share. The shares of Class A Common Stock issued in the Note Exchange are entitled to the same registration rights granted to the PIPE Investors with respect to the PIPE Shares. Refer to Note 8, *Convertible Note*, for further details of the convertible note.

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The number of shares of the Company’s common stock outstanding immediately following the consummation of the Merger was:

	Shares
Owned by Dynamics’ stockholders	14,915,963
Issued to PIPE Investors	5,060,000
Issued to Bayer in connection with convertible note cancellation and exchange	517,500
Issued to Legacy Senti stockholders.....	23,163,614
Early exercised shares subject to repurchase.....	(288,807)
Total shares of common stock immediately after Merger.....	43,368,270

⁽¹⁾ Includes 19,517,988 shares of common stock issued upon conversion of Legacy Senti’s redeemable convertible preferred stock.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Dynamics was treated as the acquired company for financial reporting purposes and Legacy Senti was treated as the acquirer. This determination was primarily based on the fact that subsequent to the Merger, the Legacy Senti stockholders hold a majority of the voting rights of the combined company, Legacy Senti comprises all of the ongoing operations of the combined company, Legacy Senti comprises a majority of the carryover governing body of the combined company, and Legacy Senti’s senior management comprises all of the senior management of the combined company. Accordingly, for accounting purposes, the Merger was treated as the equivalent of Legacy Senti issuing shares for the net assets of Dynamics, accompanied by a recapitalization. The net assets of Dynamics were stated at historical costs. No goodwill or other intangible assets were recorded. Operations prior to the Merger are those of Legacy Senti.

In connection with the Merger, the Company raised \$140.7 million in proceeds from the Merger and related PIPE Financing, including the Bayer convertible note cancellation and exchange. Transaction costs totaling \$23.5 million consisting of banking, legal, and other professional fees were deducted from the funds raised, of which \$4.8 million was incurred by the Company and the remainder by Dynamics. In addition, there were no unpaid transaction costs included in accounts payable and accrued expenses as of December 31, 2022.

4. GeneFab Transaction

On August 7, 2023, the Company entered into a framework agreement with GeneFab and Valere Bio, Inc., a Delaware corporation and the parent company of GeneFab, which is wholly owned by Celadon Partners, LLC, pursuant to which the Company, subject to the terms and conditions therein, sold, assigned and transferred its rights, title and interest in certain of the assets and contractual rights, including all of the Company’s equipment at the Company’s facilities in Alameda and certain of the Company’s non-oncology license, intellectual property related to the schematics for and design of the Alameda facility, and subleased to GeneFab its premises under the lease for the Alameda facility. The transaction will provide the Company with additional capital in the form of a note receivable and rights to future manufacturing and research activities performed by GeneFab at market rates and reduced longer term operating expenses.

Concurrently with the transaction, the Company and GeneFab entered into a development and manufacturing services agreement (the “Services Agreement”), pursuant to which GeneFab will provide certain services to the Company using the subleased Alameda facility and acquired equipment. As part of this transaction, the Company entered into a transition services agreement (“Transition Services Agreement”) with GeneFab whereby certain services are to be provided by each party to the other party during a transition period beginning on the closing of the transaction.

Under the terms of the transaction, the Company is entitled to receive total consideration of \$37.8 million before the end of 2025, of which \$18.9 million was due at closing and was netted against prepayment due to GeneFab for future manufacturing and research activities. The remaining \$18.9 million will be paid to the Company

Notes to Consolidated Financial Statements

in installments in 2024 and 2025 (the “GeneFab Note Receivable”), subject to satisfaction of certain conditions. The Company elected to account for the GeneFab Note Receivable under the fair value option and recorded the GeneFab Note Receivable at its fair value of \$16.6 million at the closing date of the transaction. The GeneFab Note Receivable will be remeasured each reporting period with changes from remeasurement included in other income (expense) in the consolidated statements of operations and comprehensive loss. Refer to Note 5. *Fair Value Measurements*.

The Company is entitled to \$18.9 million in future manufacturing and research activities to be rendered under the services agreement, which are recorded in GeneFab prepaid expenses on the consolidated balance sheet. The Company determined that the \$18.9 million for future manufacturing and research activities, inclusive of the volume discount provided, was executed at market terms and does not result in any impact to the total consideration received from GeneFab for the disposal of the business.

As part of the transaction, the Company subleased the facility in Alameda, California to GeneFab which will support the clinical manufacturing of the Company’s chimeric antigen receptor natural killer (CAR-NK) programs, including SENTI-202. Refer to Note 7. *Operating Leases* for additional information on the sublease.

The Company agreed to grant a license to GeneFab under certain of its intellectual property rights to conduct manufacturing services and to research, develop, manufacture and commercialize products outside of oncology, pursuant to a license agreement under negotiation (the “Non-Oncology License”).

In connection with the transaction, Philip Lee, Ph.D., Co-Founder and former Chief Technology Officer of the Company, assumed the role of Chief Executive Officer of GeneFab. Additionally, GeneFab extended offers of employment to 45 of the Company's employees formerly employed in its research and development and manufacturing functions. All 45 employees accepted the offers of employment and are actively engaged in providing manufacturing and research activities to the Company.

GeneFab was granted an option to purchase up to 19,633,444 shares (i.e. up to \$20.0 million worth) of the Company’s common stock at a purchase price of \$1.01867 (the “GeneFab Option”). The GeneFab Option becomes exercisable upon the execution of the license agreement, no later than August 7, 2026. The GeneFab Option may be exercised in installments of common stock equal to no more than 19.9% of the Company’s outstanding shares of common stock as of the closing date of the transaction. The purchase of the remaining shares under the GeneFab Option require stockholder approval. The Company determined that the GeneFab Option was a derivative as the terms of the instrument contain certain provisions that preclude equity classification in accordance with ASC 815. As such, the GeneFab Option was recorded as a liability at its fair value of \$9.6 million at the closing date of the transaction and subsequently remeasured with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss. Refer to Note 5. *Fair Value Measurements*.

As additional consideration for the transaction, the Company and GeneFab entered into a seller economic share agreement (the “GeneFab Economic Share”), pursuant to which the Company will be entitled to receive ten percent of the realized gains of GeneFab’s parent company arising and resulting from any cash or in-kind distributions from GeneFab in connection with a dividend or sale event, subject to the terms and conditions of the GeneFab Economic Share. The Company elected to account for the GeneFab Economic Share under the fair value option and recorded the GeneFab Economic Share at its fair value of \$1.8 million at the date of the transaction. The GeneFab Economic Share is remeasured each reporting period with changes from remeasurement included in other income (expense) in the consolidated statements of operations and comprehensive loss. Refer to Note 5. *Fair Value Measurements*.

The Company determined that GeneFab is a variable interest entity (VIE) since its total equity at risk is not sufficient to finance its activities without additional subordinated financial support. The Company performed a qualitative analysis to determine if it is the primary beneficiary of GeneFab and determined it does not have the power to direct the significant activities of GeneFab. As a result, the Company determined it is not the primary beneficiary and therefore does not consolidate GeneFab.

Refer to Note 16. *Related Parties* for GeneFab related party considerations.

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Gain on the Disposal of Business

As the assets and contractual rights transferred to GeneFab were determined to constitute a business as defined in ASC 805, *Business Combinations*, the Company accounted for the disposal by applying the derecognition guidance in ASC 810, *Consolidation*, which requires that a gain or loss be recognized for the difference between the carrying value of the assets sold and the fair value of the consideration received (or receivable).

As of August 7, 2023, the total fair value of the consideration was determined to be \$37.3 million, including the GeneFab prepaid expenses of \$18.9 million, the estimated fair value of the GeneFab Note Receivable of \$16.6 million and the estimated fair value of the GeneFab Economic Share of \$1.8 million. Out of the total consideration, \$9.6 million was allocated to the GeneFab Option, representing its estimated fair value as of the closing date.

In connection with the sale, the Company recognized a gain on disposal in the amount of \$21.9 million in net income from discontinued operations during the year ended December 31, 2023, representing the excess of the fair value of the consideration (net of the portion allocated to the GeneFab Option) over the carrying value of the assets sold of \$5.5 million. The gain on disposal was primarily related to the transfer of the non-oncology intellectual property to GeneFab which had no carrying value.

Discontinued Operations

In accordance with ASC 205, *Presentation of Financial Statements*, the Company determined that the sale of the non-oncology business, including the equipment and transfer of in-house manufacturing activities in the Alameda facility, to GeneFab represented a strategic shift that will have a major effect on the Company's operations and financial results, thus meeting the criteria to be reported as discontinued operations. Discontinued operations include the cost and depreciation of equipment and related deposits or liabilities, manufacturing personnel-related costs including costs arising as a result of the disposal such as equity award modifications and severance, and the gain from the disposal of the business. Refer to Note 9. *Stockholders' Equity (Deficit)*, for further details of the award modifications.

The following table summarizes the major classes of assets and liabilities of the discontinued operations (in thousands):

	December 31,	
	2023	2022
Prepaid expenses and other current assets	\$ —	\$ 209
Total current assets of discontinued operations	\$ —	\$ 209
.....		
Property and equipment, net	\$ —	\$ 4,775
Other long-term assets	—	10
Total non-current assets of discontinued operations	\$ —	\$ 4,785
.....		
Accounts payable.....	\$ —	\$ 897
Accrued expenses and other current liabilities	243	288
Total current liabilities of discontinued operations	\$ 243	\$ 1,185

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The following table summarizes the operating results of the discontinued operations (in thousands):

	Years Ended December 31,	
	2023	2022
Operating expenses:.....		
Research and development	\$ 10,003	\$ 5,922
General and administrative	(496)	2,623
Total operating expenses.....	9,507	8,545
Loss from discontinued operations.....	(9,507)	(8,545)
Other income (expense).....	(6)	—
Gain on disposal of business	21,861	—
Net income (loss) from discontinued operations	<u>\$ 12,348</u>	<u>\$ (8,545)</u>

General and administrative expenses were negative for the year ended December 31, 2023 due to the reversal of compensation expense for unvested awards that were cancelled due to the termination of employees subsequently hired by GeneFab. See Note 9. *Stockholders' Equity (Deficit)*.

The following table summarizes the cash flow information of the discontinued operations (in thousands):

	Years Ended December 31,	
	2023	2022
Operating activities (noncash adjustments to net income):		
Depreciation.....	\$ 185	\$ 31
Stock-based compensation expense	(2,022)	830
Gain on disposal of business.....	21,861	—
Investing activities: ⁽¹⁾		
Purchases of property and equipment	(4,079)	(1,670)
Supplemental disclosures of noncash investing items:		
Purchases of property and equipment in accounts payable and accrued expenses ..	—	3,135

⁽¹⁾ The total consideration received of \$37.8 million is a non-cash investing activity.

5. Fair Value Measurements

Cash Equivalents, Restricted Cash and Short-term Investments

The following tables summarize the estimated value of cash equivalents, restricted cash and short-term investments by category (in thousands):

	December 31, 2023						Short-term investments
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash and cash equivalents	Restricted cash	
Cash	\$ 4,205	\$ —	\$ —	\$ 4,205	\$ 4,205	\$ —	\$ —
Level 1							
Money market funds.....	\$ 35,243	\$ —	\$ —	\$ 35,243	\$ 31,721	\$ 3,522	\$ —
Subtotal.....	35,243	—	—	35,243	31,721	3,522	—
Total.....	\$ 39,448	\$ —	\$ —	\$ 39,448	\$ 35,926	\$ 3,522	\$ —
	December 31, 2022						Short-term investments
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash and cash equivalents	Restricted cash	
Level 1							
Money market funds.....	\$ 45,412	\$ —	\$ —	\$ 45,412	\$ 42,046	\$ 3,366	\$ —
Subtotal.....	45,412	—	—	45,412	42,046	3,366	—
Level 2							
U.S. Treasury securities.....	\$ 14,866	\$ 4	\$ (3)	\$ 14,867	\$ —	\$ —	\$ 14,867
U.S. agency securities.....	\$ 5,938	\$ —	\$ —	\$ 5,938	\$ 3,983	\$ —	\$ 1,955
Commercial paper.....	\$ 28,122	\$ —	\$ —	\$ 28,122	\$ 5,994	\$ —	\$ 22,128
Corporate debt securities.....	\$ 7,590	\$ 1	\$ (1)	\$ 7,590	\$ 5,598	\$ —	\$ 1,992
Subtotal.....	\$ 56,516	\$ 5	\$ (4)	\$ 56,517	\$ 15,575	\$ —	\$ 40,942
Total.....	\$ 101,928	\$ 5	\$ (4)	\$ 101,929	\$ 57,621	\$ 3,366	\$ 40,942

No securities have contractual maturities of longer than one year. There were no transfers between Levels 1, 2, or 3 for any of the periods presented.

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Contingent Earnout Liability

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	Contingent Earnout Liability
Fair value as of December 31, 2022	\$ (227)
Change in fair value included in other income (expense)	207
Fair value as of December 31, 2023	<u>\$ (20)</u>

The fair value of the Contingent Earnout Liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy.

In determining the fair value of the Contingent Earnout Liability, the Company used a Monte Carlo simulation value model using a distribution of potential outcomes. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including the current Company common stock price, expected volatility, risk-free rate, expected term and expected dividend yield. Refer to Note 9. *Stockholders' Equity (Deficit)*, for further details of the Contingent Earnout.

GeneFab Note Receivable

The following table presents a summary of the changes in the fair value of the GeneFab Note Receivable (in thousands):

	Note Receivable
Initial recognition as of August 7, 2023.....	\$ 16,614
Change in fair value included in other income (expense)	626
Fair value as of December 31, 2023	<u>\$ 17,240</u>

The fair value of the GeneFab Note Receivable is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The GeneFab Note Receivable is presented within GeneFab receivable on the consolidated balance sheet.

The Company has elected to account for the GeneFab Note Receivable under the fair value option in ASC 825, with changes in fair value reported as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The fair value of the GeneFab Note Receivable was determined by discounting future payments under multiple probability-weighted scenarios using the GeneFab's cost of borrowing, which was estimated at 13.72% as of the initial recognition date, to 12.53% as of December 31, 2023 based on published CCC-rated corporate bond yields.

GeneFab Option

The following table presents a summary of the changes in the fair value of the GeneFab Option (in thousands):

	GeneFab Option
Initial recognition as of August 7, 2023.....	\$ (9,649)
Change in fair value included in other income (expense)	3,318
Fair value as of December 31, 2023	<u>\$ (6,331)</u>

The fair value of the GeneFab Option is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy.

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In determining the fair value of the GeneFab Option, the Company used a Black-Scholes option pricing model.

The significant assumptions utilized in the valuation are described below:

	December 31, 2023	August 7 2023
Current stock price	\$ 0.66	\$ 0.90
Expected volatility	98.1%	86.0%
Risk-free interest rate	4.12%	4.44%
Expected term (years)	2.5	3.0

GeneFab Economic Share

The following table presents a summary of the changes in the fair value of the GeneFab Economic Share (in thousands):

	GeneFab Economic Share
Initial recognition as of August 7, 2023.....	\$ 1,800
Change in fair value included in other income (expense)	16
Fair value as of December 31, 2023	<u>\$ 1,816</u>

The fair value of the GeneFab Economic Share is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy.

The Company has elected to account for the GeneFab Economic Share under the fair value option in ASC 825, with changes in fair value reported as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. In determining the fair value of the GeneFab Economic Share, the Company used the option pricing method, which allocates total estimated enterprise value to various classes of equity using the Backsolve method.

The significant assumptions utilized in the valuation are described below:

	December 31, 2023	August 7 2023
GeneFab equity value (in thousands)	\$ 35,448	\$ 37,314
Volatility	65.8%	54.0%
Risk free rate	3.93%	4.23%
Expected term	4.0	4.5

6. Other Financial Statement information

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Prepaid expenses (including prepaid rent).....	\$ 2,546	\$ 1,871
Deposits	42	1,209
Other	195	101
Total prepaid expenses and other current assets	<u>\$ 2,783</u>	<u>\$ 3,181</u>

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Property and Equipment, Net

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

	December 31,	
	2023	2022
Lab equipment.....	\$ 8,186	\$ 7,855
Leasehold improvements.....	22,648	1,869
Computer equipment and software.....	360	374
Furniture and fixtures.....	326	326
Construction in progress.....	—	43,892
Property and equipment at cost.....	31,520	54,316
Less: accumulated depreciation.....	(6,182)	(2,955)
Property and equipment, net.....	<u>\$ 25,338</u>	<u>\$ 51,361</u>

Buildout of the current good manufacturing practice (cGMP) facility in Alameda was completed in June 2023 and the assets were placed in service.

As a result of the change in the manner in which the Company expects to recover the assets associated with the lease on the Alameda facility (refer to Note 4. *GeneFab Transaction*), the ROU asset and the related leasehold improvements became a separate asset group for the purposes of long-lived asset impairment assessment as of August 7, 2023. This asset group reassessment triggered a need to perform an impairment analysis. The Company concluded that the asset group was not recoverable, as the carrying value of the asset group was less than the sum of undiscounted net cash flows expected to be generated from the use of the asset group.

The Company tested the asset group for impairment and recognized an impairment loss in the amount of \$25.7 million during the year ended December 31, 2023, representing the difference between the carrying value of the asset group of \$54.6 million and its estimated fair value of \$28.9 million, determined based on the discounted cash flows expected to be generated from the use of the asset group through the sublease. Further, the Company determined that the individual fair value of the ROU asset within the asset group exceeded its carrying value as of the impairment testing date. Accordingly, the Company allocated the entire impairment loss to the leasehold improvements associated with the Alameda lease. The adjusted carrying value of the leasehold improvements of \$20.1 million will be amortized under the existing accounting policy under ASC 842, *Leases* (“ASC 842”) on a straight-line basis over the remaining lease term.

Depreciation totaled \$3.4 million and \$1.4 million for the years ended December 31, 2023 and 2022, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2023	2022
Accrued professional and service fees related to facility construction.....	\$ —	\$ 7,342
Accrued professional and service fees other.....	3,555	3,496
Accrued employee-related expenses.....	2,363	1,709
Other accrued expenses.....	9	29
Total accrued expenses and other current liabilities.....	<u>\$ 5,927</u>	<u>\$ 12,576</u>

Notes to Consolidated Financial Statements

7. Operating Leases

Lessee Accounting

The Company's operating leases are primarily for its corporate headquarters located in South San Francisco, California ("HQ lease") and for additional office and laboratory space located in Alameda, California ("Alameda lease"). The corporate headquarters lease has an initial term of eight years expiring in 2027, with an option to renew for an additional eight years unless canceled by either party thereafter. The Alameda lease has an initial term of eleven years expiring in 2032, with an option to renew the lease for up to two additional terms of five years. The exercise of these renewal options is not recognized as part of the ROU assets and lease liabilities, as the Company did not conclude, at the commencement date of the leases, that the exercise of renewal options or termination options was reasonably certain. The Alameda lease provided for a tenant improvement allowance of up to \$17.5 million for the costs relating to the design, permitting and construction of the improvements, to be disbursed by the landlord no later than December 31, 2023. The Company was deemed to be the accounting owner of the tenant improvements primarily because the Company is the principal in the construction and design of the assets, is responsible for costs overruns and retains substantially all economic benefits from the leasehold improvements over their economic lives. Accordingly, the tenant improvement allowance was considered an incentive and was deducted from the initial measurement of the ROU asset and lease liability. The Company estimated the timing of tenant improvement reimbursements at the lease commencement date and upon receipt of the cash incentives, the Company recognized the cash received as an increase in the lease liability.

A summary of total lease costs and other information for the period relating to the Company's operating leases is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Operating lease cost.....	\$ 5,277	\$ 5,300
Short-term lease cost	73	81
Variable lease cost	1,138	730
Total lease cost.....	\$ 6,488	\$ 6,111
	Years Ended December 31,	
	2023	2022
Other information:		
Operating cash flows net inflows and (outflows) from operating lease.....	\$ (2,922)	\$ 11,363
ROU assets obtained in exchange for operating lease obligations (including remeasurement of ROU and lease liabilities due to changes in the timing of receipt of lease incentives).....	\$ (5)	\$ 231
Weighted-average remaining lease term	7.5 years	8.2 years
Weighted-average discount rate	9.2%	9.1%

For the years ended December 31, 2023 and 2022, the Company received \$3.4 million and \$14.1 million, respectively, of the \$17.5 million tenant improvement allowance. Through December 31, 2023, the Company has received the full \$17.5 million tenant improvement allowance inception-to-date.

As of December 31, 2023 and 2022, amounts disclosed for ROU assets obtained in exchange for lease obligations include amounts added to the carrying amount of ROU assets resulting from lease modifications and reassessments.

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Maturities of the Company's lease liabilities as of December 31, 2023, were as follows (in thousands):

2024	\$ 7,254
2025	7,478
2026	7,712
2027	5,769
2028	4,855
Thereafter	19,529
Total undiscounted lease payments.....	<u>52,597</u>
Less imputed interest	(15,028)
Total lease liabilities	<u>\$ 37,569</u>

As of December 31, 2023, we had one letter of credit held with JPMorgan Chase Bank in the amount of approximately \$2.9 million and one letter of credit with Silicon Valley Bank, or SVB, in the amount of approximately \$0.5 million related to our facility leases.

Lessor Accounting

In connection with the GeneFab transaction, on August 7, 2023, the Company entered into a sublease with GeneFab to sublease the facility included in the Alameda lease, expiring in September 2032. Total sublease income to be earned from this operating lease, in aggregate, will be approximately \$44.1 million over the term of the sublease agreement. Sublease income was \$2.0 million for the year ended December 31, 2023. Variable sublease income was \$0.3 million for the year ended December 31, 2023. The Company records sublease income in other income (expense) in the consolidated statements of operations and comprehensive loss.

Refer to Note 16. *Related Parties* for GeneFab related party considerations.

Maturities of the Company's sublease payments from GeneFab as of December 31, 2023, were as follows (in thousands):

2024	\$ 4,345
2025	4,476
2026	4,610
2027	4,748
2028	4,891
Thereafter	18,295
Total undiscounted sublease payments	<u>\$ 41,365</u>

8. Convertible Note

On May 19, 2022, in connection with the Merger, Legacy Senti issued \$5.2 million in unsecured convertible promissory notes for the purchase price of \$5.2 million. The May 2022 Note was due May 2024 and interest accrued at an annual rate of 3.0%.

The May 2022 Note was cancellable and exchangeable or convertible under any of the following circumstances:

- Automatic conversion upon the closing of the Merger with Dynamics. The outstanding principal under this note shall be cancelled and exchanged automatically into that number of shares of Dynamics common stock as is equal to (a) the entire principal amount under this note divided by (b) \$10.00. Upon conversion of this note, any and all accrued interest under this note shall immediately and automatically be cancelled and forgiven. The shares issued upon conversion of this note shall have the same rights and entitlements as the shares issued in connection with the PIPE by Dynamics.

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- Automatic conversion upon closing of a qualified IPO. The note and any accrued unpaid interest shall be automatically converted into shares of the equity securities issued in the qualified IPO at a conversion price equal to the product of (a) 80%, and (b) the price per share of the Company's common stock issued to the public in the qualified IPO.
- Automatic conversion upon closing of non-qualified financing. The note and any accrued unpaid interest shall be automatically converted into shares of the Company's equity securities issued in such non-qualified financing at a conversion price per share equal to the product of (a) 80%, and (b) the lowest per-share selling price of the equity securities issued to other investors in the non-qualified financing.
- If the note has not been repaid or previously converted, on or after the maturity date, at the election of the holder, the outstanding balance shall either (a) be repaid in cash in an amount equal to the outstanding principal, or (b) be converted into that number of shares of Legacy Senti's Series B Preferred Stock equal to the outstanding balance divided by the original issuance price of the Series B Preferred Stock.

On June 8, 2022, concurrently with the closing of the Merger, the May 2022 Note was automatically cancelled and exchanged for 517,500 shares of Class A Common Stock at a price of \$10.00 per share.

In accordance with the accounting guidance for an extinguishment of convertible debt instruments with a conversion feature that is separately accounted for as a derivative, the Company determined that the cancellation and exchange should be accounted for as an extinguishment of the May 2022 Note and a gain on extinguishment of \$1.3 million was recorded at the closing of the Merger and all accrued interest at the time of the Merger was reversed and recorded to additional paid in capital.

9. Stockholders' Equity (Deficit)

Redeemable Convertible Preferred Stock

The Company's redeemable convertible preferred stock consisted of the following as of December 31, 2021 (in thousands, except share and per share amounts):

	December 31, 2021				
	Issue Price Per Share	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
Series A.....	\$ 1.6427	6,888,563	6,888,563	\$ 57,408	\$ 57,822
Series B.....	\$ 1.6427	12,629,427	12,629,425	114,425	106,012
Total.....		<u>19,517,990</u>	<u>19,517,988</u>	<u>\$ 171,833</u>	<u>\$ 163,834</u>

In connection with the Merger, all previously issued and outstanding redeemable convertible preferred stock was converted on June 8, 2022 into an equivalent number of shares of common stock of the Company on a one-to-one basis, then multiplied by the Exchange Ratio pursuant to the Merger Agreement. Refer to Note 3, *Reverse Recapitalization*, for further details of the Merger.

Common Stock

Holders of common stock are entitled to one vote per share, and to receive dividends and, upon liquidation or dissolution, are entitled to receive all assets available for distribution to stockholders. The holders have no preemptive or other subscription rights, and there are no redemption or sinking fund provisions with respect to such shares. Common stock is subordinate to the redeemable convertible preferred stock with respect to dividend rights and rights upon liquidation, winding up, and dissolution of the Company. Through December 31, 2023, no cash dividends have been declared or paid.

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At December 31, 2023 and December 31, 2022, the Company was authorized to issue 500,000,000 shares of common stock, all at a par value of \$0.0001 per share, and had reserved the following shares for future issuance:

	December 31,	
	2023	2022
Series A and B redeemable convertible preferred stock	—	—
Common Stock Purchase Agreement	7,327,049	8,327,049
Common stock options issued and outstanding	11,582,938	9,875,675
Restricted stock units outstanding	225,282	447,948
Common stock shares available for future issuance under equity plans	3,672,276	2,948,472
Common stock shares available for future issuance under the 2022 Employee Stock Purchase Plan (the "ESPP")	336,320	481,627
Contingent earnout common stock	2,000,000	2,000,000
GeneFab Option.....	19,633,444	—
Unvested early exercised common stock	54,860	105,500
Total	<u>44,832,169</u>	<u>24,186,271</u>

On June 8, 2022, upon the Closing, all of the outstanding redeemable convertible preferred stock was converted to Common Stock pursuant to the conversion rate effective immediately prior to the Merger and the Exchange Ratio and the remaining amount was reclassified to additional paid-in capital. Refer to Note 3. *Reverse Recapitalization*, for further details of the Merger.

Preferred Stock

In connection with the close of the Merger, the Company's Amended and Restated Certificate of Incorporation provides the Company's board of directors with the authority to issue \$0.0001 par value preferred stock in one or more series and to establish from time to time the number of shares to be included in each such series, by adopting a resolution and filing a certification of designations. Voting powers, designations, powers, preferences and relative, participating, optional, special and other rights shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and none were outstanding as of December 31, 2023 and December 31, 2022.

Notes to Consolidated Financial Statements**Common Stock Purchase Agreement**

On August 31, 2022, the Company entered into a Common Stock Purchase Agreement and a Registration Rights Agreement (collectively referred to as the “Purchase Agreement”) with Chardan Capital Markets LLC (“Chardan”). Pursuant to the Purchase Agreement, the Company has the right, in its sole discretion, to sell to Chardan up to the lesser of (i) \$50.0 million of newly issued shares of the Company’s common stock, and (ii) the Exchange Cap (as defined below) (subject to certain conditions and limitations), from time to time during the 36-month term of the Purchase Agreement. Under the applicable NASDAQ rules, the Company may not issue to Chardan under the Purchase Agreement more than 8,727,049 shares of common stock, which number of shares is equal to 19.99% of the common shares outstanding immediately prior to the execution of the Purchase Agreement unless certain exceptions are met (the “Exchange Cap”). The purchase price of the shares of common stock will be determined by reference to the Volume Weighted Average Price (“VWAP”) of the common stock during the applicable purchase date, less a fixed 3% discount to such VWAP. However, the total shares to be purchased on any day may not exceed 20% of the trading volume, and the total purchase price on any day may not exceed \$3.0 million. As consideration for Chardan’s commitment to purchase shares of common stock at the Company’s direction upon the terms and subject to the conditions set forth in the Purchase Agreement, the Company issued 100,000 shares of its common stock to Chardan and paid a \$0.4 million document preparation fee, upon execution of the Purchase Agreement. The Company recognized an expense of \$0.7 million within general and administrative expenses in the Company’s consolidated statements of operations and comprehensive loss for the Chardan related costs and legal fees incurred in connection with the execution of the agreement.

Other than the issuance of the commitment shares of the Company’s common stock to Chardan, the Company issued 1,300,000 Class A common stock through December 31, 2023 aggregating to net proceeds of \$1.2 million under the Common Stock Purchase Agreement.

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Contingent Earnout Equity

Following the closing of the Merger, former holders of Legacy Senti common stock and preferred stock may receive up to 2,000,000 additional shares of the Company’s common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche. The first and second tranches are issuable if the closing volume weighted average price (“VWAP”) per share of common stock quoted on the Nasdaq (or the exchange on which the shares of common stock are then listed) is greater or equal to \$15.00 and \$20.00, respectively over any twenty trading days within any thirty-day trading period. The first and second tranche term is two and three years, respectively, from the closing of the Merger. If there is a change of control within the three-year following the closing of the Merger that results in a per share price equal to or in excess of the \$15.00 and \$20.00 share price milestones not previously met, then Company shall issue the earnout shares to the holders of Legacy Senti common stock and preferred stock.

The estimated fair value of the total Contingent Earnout Shares at the Closing on June 8, 2022, was \$9.8 million based on a Monte Carlo simulation valuation model. Of this amount, \$9.7 million was accounted for as a Contingent Earnout Liability because the triggering events that determine the number of Contingent Earnout Shares required to be issued include events that are not solely indexed to the common stock of the Company. The remaining balance of \$0.1 million relates to holders of Legacy Senti common stock that are subject to repurchase were accounted for as stock-based compensation expense and recorded as an expense, as there was no remaining service period. The Contingent Earnout Liability was remeasured to fair value, resulting in the recording of a non-cash gain of \$0.2 million for the year ended December 31, 2023 and non-cash gain of \$9.5 million for the year ended December 31, 2022, classified within change in fair value of contingent earnout liability in the consolidated statements of operations and comprehensive loss.

Assumptions used in the valuation are described below:

	December 31,	
	2023	2022
Current stock price	\$ 0.66	\$ 1.41
Expected share price volatility.....	113.5%	85.0%
Risk-free interest rate.....	4.51%	4.32%
Estimated dividend yield	0.0%	0.0%
Expected term (years).....	1.5	2.4

10. Revenue

The Company’s revenue consists of amounts received related to research services provided to customers.

Contract Revenue

In April 2021, the Company entered into a research collaboration and license agreement with Spark Therapeutics, Inc. (“Spark”). Under the agreement, the Company will be responsible for a research program, which includes designing, building and testing five cell type specific-synthetic promoters for use in developing certain gene therapies using the Company’s proprietary technology. The Company received an upfront payment from Spark of \$3.0 million and Spark is obligated to reimburse the Company for costs and expenses incurred for the research program. The Company expected to complete the research program over a two-year period.

The Company assessed this agreement in accordance with ASC 606, *Revenue Recognition* (“ASC 606”) and concluded that the contract counterparty, Spark, is a customer. The Company identified only one combined performance obligation in the agreement, which is to perform research services, the related joint research plan and committees for the five specified promoters. The Company determined that the research activities for each of the five promoters are not distinct given there is one single research plan that is performed by the same research team and research results for one promoter may provide insights for other promoters.

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Pursuant to the agreement, once the research program is completed and the Company delivers a data package to Spark, Spark has 24 months (the “Evaluation Period”) to determine whether Spark will exercise its options to obtain field-limited, royalty-bearing licenses to develop, manufacture and commercialize promoters corresponding to each of the five specified promoters being researched. For each licensed promoter option that is exercised, the Company is eligible to receive a license fee, potential research, development and commercial milestone payments and royalties on product sales. Spark may generally terminate the agreement upon 90 days prior written notice or 180 days prior written notice if the licensed promoter is in clinical trials or is being commercialized at the time of termination.

The Company evaluated Spark’s optional rights to license, develop, manufacture and commercialize each of the promoter profiles to determine whether they provide Spark with any material rights to purchase the promoter licenses at an incremental discount. The Company’s proprietary technology used to develop the promoters is in the early stages of development, so technological feasibility and probability of developing a product is highly uncertain. As a result, determining the SSP for the optional rights is subject to significant judgment. Given the subjectivity associated with determining the SSP for the right to a future license related to unproven technology at contract inception, the Company also evaluated whether the contract consideration associated with the research services represents the SSP for those services. The Company determined the transaction price, inclusive of the upfront payment and reimbursement of costs and expenses incurred for the research program, is commensurate with SSP for the research being conducted given the specialized nature and reliance on proprietary technology. Based on the Company’s assessment of the optional consideration and the qualitative factors of feasibility and probability of development combined with the quantitative assessment that research services are priced at their SSP, the Company concluded that the license option does not provide Spark with an incremental discount and therefore does not constitute a material right. The transaction price associated with the research services in this agreement consists of the fixed upfront amount of \$3.0 million and variable consideration.

For the Spark collaboration agreement, the Company will recognize the transaction price as research and development services are provided, using a cost-based input method to measure the progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes that the cost-based input method is the best measure of progress because other measurements would not reflect how the Company transfers the control related to the performance obligation to our customers.

In December 2022, the Company amended the research collaboration and license agreement to allow for an increase in budget and a two-month extension of the research program. As there were no changes to performance obligations and the services to be provided are not distinct from those already transferred, the transactions was accounted for as a contract modification and a cumulative catch-up of \$(0.7) million was recognized in December 2022.

In May 2023, the Company amended the research collaboration and license agreement with Spark to allow for an increase in budget and additional two-month extension of the research program. As there were no changes to performance obligations and the services to be provided are not distinct from those already transferred, the transaction was accounted for as a contract modification with no cumulative catch-up necessary.

In July 2023, the Company completed the research program under the research collaboration and license agreement with Spark and the remaining upfront payment was recognized.

As of December 31, 2023 there was no remaining upfront payment and as of December 31, 2022 there was \$0.8 million remaining of the upfront payment to be recognized over the remaining period of the research program.

In November 2023, the Company entered into a Collaboration and Option Agreement with Celest Therapeutics (Shanghai) Co. Ltd. (“Celest”). Subject to the terms and conditions of the Agreement, the Company and Celest will enter into a collaboration under which Celest will lead a pilot trial of a candidate product for the SENTI-301A program in mainland China, with certain technical support from the Company. In addition, the Company agreed to grant an exclusive option to enter a license agreement with Celest to research, develop, manufacture and commercialize SENTI-301A in mainland China, Hong Kong, Macau, and Taiwan. Outside of these jurisdictions, the Company would retain its rights in the SENTI-301A program. Pursuant to the Agreement, with the exercise of the

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option and entering into a license agreement, the Company may become eligible to receive certain option exercise fee and milestone payments, in an aggregate amount of \$156.0 million, as well as certain tiered royalty payments.

For the years ended December 31, 2023 and 2022, the Company recorded revenue, which was previously included in the deferred revenue at the beginning of each period, of \$0.8 million and \$1.0 million, respectively.

Grant Income

In 2021, the Small Business Innovation Research (“SBIR”) awarded the Company a grant in the amount of \$2.0 million over two years subject to meeting certain terms and conditions. The purpose of the grant is to support the further development of SENTI-202 for acute myeloid leukemia towards clinical development.

Grant income was recognized when qualified research and development costs were incurred and the Company obtained reasonable assurance that the terms and conditions of the grant were met.

In August 2023, the Company completed the research and development project which was the subject of the SBIR grant.

Entity-wide information

During both years ended December 31, 2023 and 2022, Customers A and B accounted for 77% and 23%, respectively, of revenue.

All revenues were generated in the United States for the years ended December 31, 2023 and 2022.

11. Stock-Based Compensation

2016 Stock Incentive Plan (as Amended and Restated)

The Company’s 2016 Stock Incentive Plan (the “2016 Plan”) provides for the grant of incentive stock options, non-qualified stock options and restricted stock awards to employees, directors, and consultants of the Company.

Stock options granted under the 2016 Plan generally vest over four years and expire no later than ten years after the grant date.

Following the Merger, the 2016 Plan was terminated. No additional stock awards will be granted under the 2016 Plan. All awards previously granted and outstanding as of the effective date of the Merger, were adjusted to reflect the impact of the Merger, but otherwise remain in effect pursuant to their original terms. The shares underlying any award granted under the 2016 Plan that are forfeited back to or repurchased or reacquired by the Company, will revert to and again become available for issuance under the 2022 Plan.

2022 Stock Incentive Plan

On June 8, 2022, upon the Merger, the Company adopted a 2022 Stock Incentive Plan (the “2022 Plan”). The 2022 Plan provides for the grant of incentive stock options to employees, and for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants.

The exercise price of an options granted under the 2022 Plan shall not be less than the fair market value of a common stock share on the date of grant. With respect to a 10% stockholder, the exercise price of an option granted shall not be less than 110% of the fair value of the common stock share on the date of grant.

Options granted under the 2022 Plan generally vest over four years and expire no later than ten years after the grant date.

The Company initially reserved 2,492,735 shares of common stock for issuance under the 2022 Plan. On the first day of each year commencing January 1, 2023, the 2022 Plan will automatically increase by 5% of the outstanding number of shares of common stock of the Company on the last day of the preceding calendar year or

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such lesser number of shares as approved by the Company's board of directors prior to the effective date of the annual increase. In addition, the shares underlying any award granted under the 2016 Plan that are forfeited back to or repurchased or reacquired by the Company, will revert to and again become available for issuance under the 2022 Plan.

As of December 31, 2023, the total number of shares of common stock available for issuance under the 2022 Plan is 2,419,363.

2022 Inducement Equity Plan

On August 5, 2022, the Company adopted a 2022 Inducement Equity Plan (the "2022 Inducement Plan"). The 2022 Plan provides for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to persons not previously an employee of the Company and its affiliates.

The exercise price of an options granted under the 2022 Inducement Plan shall not be less than the fair market value of a common stock share on the date of grant.

Stock options granted under the 2022 Inducement Plan generally vest over four years and expire no later than ten years after the grant date.

The Company initially reserved 2,000,000 shares of common stock for issuance under the 2022 Inducement Plan.

As of December 31, 2023, the total number of shares of common stock available for issuance under the 2022 Inducement Plan is 1,252,913.

2022 Employee Stock Purchase Plan

On June 8, 2022, upon the Merger, the Company adopted a 2022 Employee Stock Purchase Plan (the "ESPP"). The ESPP allows eligible employees to purchase shares of the Company's common stock at a price equal to 85% of the lower of the fair market values of the stock on the first day of an offering or on the date of purchase. The Company's ESPP operates with rolling offering periods, which are generally 24 months. On November 15, 2023, upon termination of the then-current offering period in accordance with the terms of the ESPP, the Company suspended the ESPP and no new offering periods may commence under the ESPP until such time as later authorized by the Company.

The Company initially reserved 592,584 shares of common stock for issuance under the ESPP. On the first day of each year commencing January 1, 2023, the 2022 Plan will automatically increase by 1% of the outstanding number of shares of common stock of the Company on the last day of the preceding calendar year or such lesser number of shares as approved by the Company's board of directors prior to the effective date of the annual increase.

As of December 31, 2023, the total number of shares of common stock available for issuance under the ESPP is 336,320.

SENTI BIOSCIENCES, INC.

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Stock Options

The following table summarizes the Company's stock option activity and related information under all equity plans, excluding performance and market awards:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	4,191,426	\$ 3.18	9.1	\$ 6
Granted	2,914,196	\$ 1.60		
Forfeited.....	(869,943)	\$ 3.33		
Outstanding at December 31, 2023	6,235,679	\$ 2.42	7.2	\$ 2
Vested and exercisable at December 31, 2023.....	2,270,135	\$ 3.00	6.7	\$ 2

The weighted-average grant date fair value of options granted during the years ended December 31, 2023 and 2022 were \$1.14 and \$1.47, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 were \$0.0 million and \$0.3 million, respectively.

As of December 31, 2023 and 2022, the unrecognized stock-based compensation expense related to stock options was approximately \$5.2 million and \$8.0 million respectively, expected to be recognized over a weighted-average period of 2.16 years and 2.7 years respectively.

Early Exercise of Stock Options into Restricted Stock

For the years ended December 31, 2023 and 2022, the Company issued zero shares of common stock upon exercise of unvested stock options. As of December 31, 2023 and December 31, 2022, 54,860 and 105,500 shares were held by employees subject to repurchase at an aggregate price of \$0.1 million and \$0.3 million, respectively.

Performance Awards

In connection with the Merger, on December 19, 2021, Legacy Senti approved 8,400,892 performance awards to existing employees that vest contingent upon the satisfaction of both a four-year service condition and a performance condition tied to the consummation of the Merger. The awards and the associated recognition of stock-based compensation expense were contingent on the Merger being consummated. As of the approval date of the performance awards, Legacy Senti did not have sufficient common stock available for issuance. Upon the Merger, the Company increased the number of shares authorized and 6,796,074 awards were granted on June 8, 2022.

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	5,368,501	\$ 9.92	9.0	\$ —
Granted	—	\$ —		
Forfeited.....	(336,990)	\$ 9.92		
Outstanding at December 31, 2023	5,031,511	\$ 9.92	7.5	\$ —
Vested and exercisable at December 31, 2023.....	2,009,756	\$ 9.92	7.3	\$ —

There were no performance based options granted or exercised during the year ended December 31, 2023, and there were 6,796,074 performance based options granted and no performance based options exercised during the year ended December 31, 2022.

As of December 31, 2023, the unrecognized stock-based compensation expense related to performance awards was approximately \$3.6 million, expected to be recognized over a weighted-average period of 1.52 years.

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Market Awards

In connection with the Merger, on December 19, 2021, Legacy Senti approved 605,451 market award options to its co-founder and Chief Executive Officer, Dr. Timothy Lu, that vest contingent upon the satisfaction of all three of the following conditions: a service condition, a performance condition tied to the consummation of the Merger, and market conditions. The market condition is achieved in four tranches, where 25% of the options will vest when the trading price of the Company’s stock is above various thresholds of price per share. The award and the associated recognition of stock-based compensation were contingent on the Merger being consummated. The estimated fair value of the market awards at the grant date was based on a Monte Carlo simulation valuation model. As of the approval date, Legacy Senti did not have sufficient common stock available for issuance to allow for exercise of the stock options. Upon the Merger, the Company increased the number of shares authorized and 315,748 awards were granted on June 8, 2022. Through December 31, 2023, these market awards did not meet the vesting thresholds.

There were no market based options granted or exercised during the year ended December 31, 2023, and there were 315,748 market based options granted and no market based options exercised during the year ended December 31, 2022.

As of December 31, 2023, the unrecognized stock-based compensation expense related to market awards was approximately \$0.2 million, expected to be recognized over a weighted-average period of 0.63 years.

Restricted Stock Units

The following table summarizes the Company’s restricted stock units activity and related information under all equity plans:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	447,948	\$ 2.50
Forfeited.....	(222,666)	\$ —
Outstanding at December 31, 2023	<u>225,282</u>	<u>\$ 2.50</u>

As of December 31, 2023, the unrecognized stock-based compensation expense related to restricted stock units was approximately \$0.2 million, expected to be recognized over a weighted-average period of 0.72 years.

Stock-Based Compensation Expense

The Company estimates the fair value of stock options using a Black-Scholes option-pricing model. The fair value of restricted stock is based on the fair value of the Company’s common stock on the grant date.

The Company uses the assumptions below for the Black-Scholes option pricing model, which are subjective and generally require significant judgment.

Fair Value of Common Stock — The fair value of the shares of common stock has historically been determined by the Company’s board of directors as there was no public market for the common stock. The board of directors determined the fair value of the common stock by considering a number of objective and subjective factors, including: third-party valuations of the Company’s common stock, the valuation of comparable companies, the Company’s operating and financial performance, and general and industry-specific economic outlook, amongst other factors. As of the closing of the Merger and going forward, the fair value of common stock will be based on the publicly traded market value.

Expected Term — The expected term represents the period that the Company’s stock options are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). The expected term for the ESPP purchase rights is the length of the purchase period.

SENTI BIOSCIENCES, INC.

Notes to Consolidated Financial Statements

Volatility — The expected volatility is based on the average historical volatility of comparable publicly-traded peer companies, over a period equal to the expected term of the stock option grants, as the Company was not publicly traded prior to the Merger and does not have a trading history for its common stock for a sufficient period of time subsequent to the Merger.

Risk-free Rate — The risk-free rate assumption is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividends — The Company has never paid dividends on its common stock and does not anticipate paying dividends on common stock. Therefore, the Company uses an expected dividend yield of zero.

The assumptions used to determine the grant date fair value of non-market based, stock options granted were as follows, presented on a weighted-average basis:

	Years Ended December 31,	
	2023	2022
Expected term (in years).....	5.9	5.8
Expected volatility.....	82.6%	78.8%
Risk-free interest rate.....	3.6%	3.2%
Dividend yield.....	—	—

Total stock-based compensation expense was as follows (in thousands):

	Years Ended December 31,	
	2023	2022
General and administrative.....	\$ 10,236	\$ 13,340
Research and development.....	1,456	2,222
Total stock-based compensation expense.....	<u>\$ 11,692</u>	<u>\$ 15,562</u>

In August 2023, in connection with the GeneFab transaction, the Company's board of directors approved the modification of equity awards as part of termination of employment for the Company's employees transferred to GeneFab, including the Company's Chief Technology Officer. The award modifications included the acceleration of certain non-vested stock options and the extension of the post-termination exercise period of certain vested stock options. The Company accounted for the award modifications under ASC 718, *Compensation – Stock Compensation*. During year ended December 31, 2023, the Company recorded a one-time, noncash incremental compensation expense net of the required reversal of previously recognized compensation attributed to non-vested awards in the amount of \$2.0 million related to the equity awards modifications of the employees that were extended offers of employment by GeneFab which was included in net income from discontinued operations in the consolidated statements of operations and comprehensive loss.

Total stock-based compensation expense from discontinued operations was \$(2.0) million and \$0.8 million for the years ended December 31, 2023 and 2022, respectively.

12. Income Tax

The Company did not record any income tax expense or benefit during the years ended December 31, 2023 and 2022. The Company has a net operating loss and has provided a valuation allowance against net deferred tax assets due to uncertainties regarding the Company's ability to realize these assets.

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Notes to Consolidated Financial Statements

For the calendar years ended December 31, 2023 and 2022, the tax effects of significant items comprising the Company's deferred taxes are as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	\$ 33,566	\$ 25,249
Capitalized R&D Section 174 expense	10,146	5,131
Tax credits	9,237	6,053
Lease liability	6,005	7,789
Stock-based compensation	4,785	683
Accruals and reserves	724	756
Related Party Fair Value Adjustment	346	—
Fixed asset basis	—	259
Total deferred tax assets	64,809	45,920
Deferred tax liabilities:		
Operating lease right-of-use assets	(1,548)	(3,869)
Fixed asset basis	(2,008)	—
Total deferred tax liabilities	(3,556)	(3,869)
Valuation allowance	(61,253)	(42,051)
Net deferred taxes	\$ —	\$ —

The Company records the tax benefit of net operating losses, temporary differences, and credit carryforwards as assets to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

The valuation allowance increased by approximately \$19.2 million and \$12.3 million during years ended December 31, 2023 and 2022, respectively, and the Company's deferred tax assets continue to be fully offset by the valuation allowance as at December 31, 2023. For the years ended December 31, 2023 and 2022, the Company did not record an income tax provision.

Net operating losses and tax credit carryforwards as of December 31, 2023 are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	\$ 132,504	Do Not Expire
Net operating losses, federal (Pre January 1, 2018)	\$ 3,508	12/31/2036
Net operating losses, state	\$ 71,637	12/31/2036
Tax credits, federal	\$ 6,670	12/31/2038
Tax credits, state	\$ 5,605	Do Not Expire

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed an analysis to determine the limitation of our net operating loss carryforwards.

SENTI BIOSCIENCES, INC.

Notes to Consolidated Financial Statements

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	Years Ended December 31,	
	2023	2022
Statutory rate	21.00%	21.00%
State tax	3.30%	(0.13)%
Other	(0.86)%	(0.93)%
Tax credits	3.37%	1.21%
Fair value of series B preferred stock tranche obligation	—%	—%
Fair value of contingent earnout liability.....	1.04%	3.41%
Valuation allowance.....	(27.84)%	(24.56)%
Total.....	—%	—%

The Company has elected to include interest and penalties as a component of tax expense. For the years ended December 31, 2023 and 2022, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

The Company files income tax returns in federal and various state jurisdictions where a filing obligation has been determined. The federal and state income tax returns from inception to December 31, 2023 remain subject to examination.

The Company had \$2.1 million of unrecognized tax benefits as of December 31, 2023. No liability related to uncertain tax positions is recorded on the financial statements as all uncertain tax positions are currently recorded as a reduction to the Company's deferred tax assets, which are subject to a valuation allowance. If recognized, none of the unrecognized tax benefits would affect the effective tax rate. The Company does not anticipate the total amounts of unrecognized tax benefits will significantly increase or decrease in the next 12 months. No positions were settled with tax authorities in 2023 and no positions were reduced as a result of a lapse of applicable statutes of limitations. The Company's policy is to include interest and penalties related to unrecognized tax benefits within the provision for income taxes, as necessary. The Company did not recognize any accrued interest and penalties related to gross unrecognized tax benefits related to the year ended December 31, 2023. A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2023 and 2022 is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Balance at beginning of the year	\$ 1,643	\$ 1,252
Decrease related to prior year tax positions.....	(243)	(109)
Increase related to current year tax positions.....	676	500
Balance at end of the year.....	\$ 2,076	\$ 1,643

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Notes to Consolidated Financial Statements

13. Net Loss Per Share

A reconciliation of net loss available to common stockholders and the number of shares in the calculation of basic and diluted loss per share is as follows (in thousands, except share and per share amounts):

	Years Ended December 31,	
	2023	2022
Net loss from continuing operations.....	\$ (83,406)	\$ (49,665)
Net income (loss) from discontinued operations	12,348	(8,545)
Net loss	<u>\$ (71,058)</u>	<u>\$ (58,210)</u>
Weighted-average shares used in computing net loss per share, basic and diluted.....	44,372,223	26,110,785
Net loss per share from continuing operations, basic and diluted.....	\$ (1.88)	(1.90)
Net income (loss) per share from discontinued operations, basic and diluted.....	0.28	(0.33)
Net loss per share attributable to common stockholders, basic and diluted.....	<u>\$ (1.60)</u>	<u>\$ (2.23)</u>

The following potential common stock securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive (on an as-converted basis):

	Years Ended December 31,	
	2023	2022
Stock options to purchase common stock.....	11,582,938	9,875,675
Unvested early exercised options	54,860	105,500
Restricted stock units outstanding	225,282	447,948
Contingent earnout common stock	2,000,000	2,000,000
GeneFab Option.....	19,633,444	0
Total	<u>33,496,524</u>	<u>12,429,123</u>

14. Retirement Plan

The Company maintains a defined contribution employee retirement plan, or 401(k) plan, for all employees upon their date of hire. The 401(k) plan is intended to qualify as tax-qualified plans under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan permit employees to contribute, on a pre-tax basis, a portion of their salary up to the Federally mandated limits. The Company matches an employee’s contribution up to 4% of the employee’s compensation. Contributions to the plans by the Company totaled \$0.7 million and \$0.6 million, respectively, for the years ended December 31, 2023 and 2022.

15. Commitments and Contingencies

In the ordinary course of business, the Company enters into contractual agreements with third parties that include non-cancelable payment obligations, for which the Company is liable in future periods.

On June 3, 2021, the Company entered into a lease agreement for a new cGMP facility in Alameda, California to support planned initial clinical trials for our product candidates. Refer to Note 7. *Operating Leases*, for further details of the leases. The lease will expire in 2032 with future undiscounted operating lease payments of \$46.0 million over an initial lease period of eleven years.

In 2021, the Company entered into a three-year collaboration and option agreement with BlueRock Therapeutics LP (“BlueRock”) under which the Company granted BlueRock an option to acquire an exclusive or non-exclusive license to develop, manufacture and commercialize cell therapy products. Refer to Note 16. *Related*

Notes to Consolidated Financial Statements

Parties, for further details of the related parties. In consideration for the option, the Company is responsible for up to \$10.0 million in costs and expenses incurred over the three-year term.

As of December 31, 2023, purchase commitments related to sponsored research agreements amounted to approximately \$0.3 million.

The Company has entered into license agreements under which they are obligated to make annual maintenance payments of \$0.2 million and specified milestone and royalty payments. Future milestone and royalty payments under these agreements are not considered contractual obligations since the payments under these agreements are contingent upon future events, such as the Company's achievement of specified development, regulatory, and sales milestones, or generating product sales. As of December 31, 2023, the Company is unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

In connection with the Merger, former holders of Legacy Senti common stock and preferred stock may receive up to 2,000,000 additional shares of the Company's common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche. Refer to Note 9. *Stockholders' Equity (Deficit)*, for further details of the contingent earnout liability.

Legal Proceedings

The Company is subject to claims and assessments from time to time in the ordinary course of business but does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's financial position, results of operations, or cash flows.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions and has never accrued any liabilities related to such obligations in its consolidated financial statements. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

16. Related Parties***NEA***

NEA held 4,426,151 shares of common stock as of December 31, 2023 and 2022. NEA held one of the six seats and one of the seven seats on the Company's board of directors as of December 31, 2023 and 2022, respectively.

Bayer Healthcare LLC

On May 19, 2022, Legacy Senti issued to Bayer a \$5.2 million unsecured convertible promissory note. On June 8, 2022, the May 2022 Note was automatically cancelled and exchanged for 517,500 shares of Class A Common Stock at a price of \$10.00 per share. Refer to Note 8. *Convertible Note*, for further details of the convertible note.

On May 21, 2021, the Company entered into a collaboration and option agreement ("BlueRock Agreement") with BlueRock, a wholly-owned subsidiary of Bayer, pursuant to which the Company granted to BlueRock an option ("BlueRock Option"), on a collaboration program-by-collaboration program basis, to obtain an exclusive or non-exclusive license to develop, manufacture and commercialize cell therapy products that contain cells of specified types and which incorporate an option gene circuit from such collaboration program or a closely related derivative gene circuit. The Company is responsible for up to \$10 million in costs and expenses incurred in

Notes to Consolidated Financial Statements

connection with the research plan and related activities to be conducted over a term of three years as specified in the collaboration and option agreement. If the Company and BlueRock agree to add new research activities to the research plan, then BlueRock will be obligated to reimburse the Company for the costs and expenses incurred that, together with costs and expenses incurred under the initial research plan, exceed \$10 million.

The Company concluded that the Agreement is not within the scope of ASC 808, *Collaborative Arrangements*, because the Company did not receive any consideration and therefore, is not exposed to both significant risks and rewards for the arrangement. The Company also determined that the agreement is also not currently within the scope of ASC 606 because the BlueRock Agreement does not currently meet the criteria of a contract with a customer, and will not be within the scope of ASC 606 until any consideration is paid. Potential future milestone payments and royalties are subject to BlueRock's exercise of the BlueRock Option and execution of a commercial license agreement by both parties. Under the BlueRock Agreement, the specific financial terms for milestone payments and royalties will be negotiated and agreed to only after the option is exercised.

Bayer held 5,878,488 shares of the Company's common stock as of December 31, 2023 and 2022. Accordingly, Bayer is considered a related party.

Seer, Inc.

In January 2023, the Company acquired lab automation equipment purchased from Seer, Inc. ("Seer") (NASDAQ: SEER). Omid Farokhzad, a member of the Company's board of directors is the Chief Executive Officer for Seer. The consideration of \$0.2 million, plus interest, will be paid over a two-year period, and title will transfer to the Company upon final payment. The transaction was classified as a finance lease in accordance with ASC 842.

GeneFab, LLC.

As a result of the transaction with GeneFab (refer to Note 4. *GeneFab Transaction*), the Company received the GeneFab Note Receivable and the GeneFab Economic Share and provided GeneFab with the GeneFab Option. Refer to Note 5. *Fair Value Measurements*.

The Company also subleased its manufacturing facility in Alameda to GeneFab and recorded sublease income of \$2.3 million including variable costs charged for the year ended December 31, 2023. As of December 31, 2023, the Company had \$1.5 million of charges related to the Transition Services Agreement, sublease rent and other charges due from GeneFab which are included in GeneFab receivable on the consolidated balance sheet.

In connection with the services agreement entered into with GeneFab, the Company is entitled to \$18.9 million for future services under the agreement, of which \$14.8 million remained in GeneFab prepaid expenses as of December 31, 2023. Additionally, amounts due from GeneFab related to costs incurred by the Company on its behalf were \$1.4 million as of December 31, 2023 and were recorded in GeneFab receivable on the consolidated balance sheet. The Company incurred \$3.1 million of research and development expenses under the services agreement during the year ended December 31, 2023.

Based on the intricacies of the GeneFab Transaction noted above and in Note 4. *GeneFab Transaction*, we have determined that GeneFab is a related party.

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Notes to Consolidated Financial Statements

17. Subsequent Events

Reduction in Force

On January 5, 2024, the Company announced a reduction of approximately 37% of its workforce in connection with the Company's plans to streamline its business operations to enable increased focus on SENTI-202 and to continue with the clinical development of its SENTI-301A program through a partnership in China. The Company incurred certain one-time estimated severance and related costs as part of this resource allocation effort.

NASDAQ Bid Price Compliance Notice

On January 23, 2024, the Company received written notice from the Listing Qualifications Department granting the Company its request to transfer the listing of its common stock from The Nasdaq Global Market tier to The Nasdaq Capital Market tier, effective January 25, 2024. On February 6, 2024, the Listing Qualifications Department granted the Company's request for a second 180-calendar day period, or until August 5, 2024, to regain compliance with the \$1.00 bid price requirement.

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

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer and principal accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) to determine whether such disclosure controls and procedures provide reasonable assurance that information to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and such information is accumulated and communicated to management, including our principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding disclosure. Our disclosure controls and procedures were developed through a process in which our management applied its judgment in assessing the costs and benefits of such controls and procedures, which, by their nature, can provide only reasonable assurance regarding the control objectives. You should note that the design of any system of disclosure controls and procedures is based in part upon various assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

As previously reported, in connection with our preparation and the audit of our consolidated financial statements as of and for the year ended December 31, 2022, we and our independent registered public accounting firm identified a material weakness, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. The material weakness related to a lack of sufficient and adequate resources in the finance and accounting function that resulted in 1. lack of formalized risk assessment process, 2. lack of segregation of duties, and 3. ineffective process level control activities over (a) management review of journal entries, (b) account reconciliations and (c) non-routine, unusual or complex transactions. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

Remediation Efforts to Address the Material Weakness

Based on the remediation efforts described below, material weakness 1, 2, 3(a) and (b) noted above, has been fully remediated as of December 31, 2023, and while substantial progress has been made related to material weakness 3(c), further actions and testing are necessary before we can conclude full remediation. Remediation efforts to date include the following:

- engaging a professional accounting services firm to help us commence the documentation and assessment of our internal controls for complying with the Sarbanes-Oxley Act;
- implementing a risk assessment over financial reporting controls; and
- implementing new software tools.

While significant progress has been made to enhance our internal control over financial reporting, we are still in the process of building and enhancing our processes, procedures, and controls. Additional time is required to complete the remediation over ineffective process level control activities over non-routine, unusual and complex transactions to ensure the sustainability of these remediation actions. As such, we have not concluded that the material weakness has been fully remediated as of December 31, 2023, and therefore have concluded that our disclosure controls and procedures were not effective as of December 31, 2023.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a 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 management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with U.S. GAAP. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all errors and all fraud. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with our policies and procedures may deteriorate. Our management, under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was not effective due to the material weaknesses described above.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K 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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information regarding executive officers and executive officers and directors required by this Item 10 will be included in the 2024 Proxy Statement or in an amendment on Form 10-K/A and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in the 2024 Proxy Statement or in an amendment on Form 10-K/A and is incorporated herein by reference.

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

The information required by this Item 12 will be included in the 2024 Proxy Statement or in an amendment on Form 10-K/A 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 the 2024 Proxy Statement or in an amendment on Form 10-K/A and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in the 2024 Proxy Statement or in an amendment on Form 10-K/A and is incorporated herein by reference.

Our independent registered public accounting firm is KPMG LLP, San Francisco, CA, Auditor ID: 185.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibit Number	Description	Incorporated by Reference		
		Schedule/Form	File No.	Exhibit
2.1 [^]	Business Combination Agreement, dated as of December 19, 2021, by and among Dynamics Special Purpose Corp., Explore Merger Sub, Inc. and Senti Biosciences, Inc. (attached as Annex A to the Registration Statement).	S-4/A	333-262707	2.1
2.2 [^]	Amendment No. 1 to Business Combination Agreement, dated as of February 12, 2022, by and among Dynamics Special Purpose Corp., Explore Merger Sub, Inc. and Senti Biosciences, Inc. (attached as Annex AA to the Registration Statement).	S-4/A	333-262707	2.2
2.3 [^]	Amendment No. 2 to Business Combination Agreement, dated as of May 19, 2022, by and among Dynamics Special Purpose Corp., Explore Merger Sub, Inc. and Senti Biosciences, Inc.	8-K	001-40440	2.1
3.1	Second Amended and Restated Certificate of Incorporation of Senti Biosciences, Inc.	8-K	001-40440	3.1
3.2	Amended and Restated Bylaws of Senti Biosciences, Inc.	8-K	001-40440	3.2
4.1	Specimen Common Stock Certificate.	8-K	001-40440	4.1
4.3	Description of Securities	10-K	001-40440	4.3
10.1	Note Subscription Agreement by and among Senti Biosciences, Inc., Dynamics Special Purpose Corp. and Bayer HealthCare LLC, dated as of May 19, 2022.	8-K	001-40440	10.1
10.2+	Senti Biosciences, Inc. 2016 Stock Incentive Plan, as amended, and forms of award agreements thereunder.	S-4	333-262707	10.2
10.3+	Senti Biosciences, Inc. 2022 Equity Incentive Plan and forms of award agreements thereunder.	10-Q	001-40440	10.3
10.4+	Senti Biosciences, Inc. 2022 Employee Stock Purchase Plan.	10-Q	001-40440	10.4
10.5+	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers. Combination.	S-4/A	333-262707	10.5
10.6+	Employee Offer Letter, by and between Timothy Lu and Senti Biosciences, Inc., dated December 27, 2018.	S-4	333-262707	10.6
10.7+	Employee Offer Letter, by and between Philip Lee and Senti Biosciences, Inc., dated December 27, 2018.	S-4	333-262707	10.7
10.8+	Employee Offer Letter, by and between Deborah Knobelman and Senti Biosciences, Inc., dated May 13, 2021.	S-4	333-262707	10.9

Exhibit Number	Description	Schedule/Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
10.9	Lease, by and between Britannia Biotech Gateway Limited Partnership and Senti Biosciences, Inc., dated July 17, 2018.	S-4	333-262707	10.10	February 14, 2022
10.10	First Amendment to Lease, by and between Britannia Biotech Gateway Limited Partnership and Senti Biosciences, Inc., dated May 8, 2019.	S-4	333-262707	10.11	February 14, 2022
10.11	Second Amendment to Lease, by and between Britannia Biotech Gateway Limited Partnership and Senti Biosciences, Inc., dated June 17, 2020.	S-4	333-262707	10.12	February 14, 2022
10.12†	Research and Development and Laboratory Lease Agreement, by and between 1430 Harbor Bay Pkwy LLC and Senti Biosciences, Inc., dated June 3, 2021.	10-K	001-40440	10.13	March 22, 2023
10.13†	Patent License Agreement by and between the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, and Senti Biosciences, Inc., dated July 20, 2020.	S-4	333-262707	10.14	February 14, 2022
10.14†	Patent License Agreement by and between the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, and Senti Biosciences, Inc., dated February 5, 2021.	S-4	333-262707	10.15	February 14, 2022
10.15†	Research Collaboration and License Agreement by and between Spark Therapeutics, Inc. and Senti Biosciences, Inc., dated April 9, 2021.	S-4	333-262707	10.16	February 14, 2022
10.16†	Patent License Agreement by and between the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, and Senti Biosciences, Inc., dated May 17, 2021.	S-4	333-262707	10.17	February 14, 2022
10.17†	Collaboration and Option Agreement by and between BlueRock Therapeutics, LP and Senti Biosciences, Inc., dated May 21, 2021.	S-4	333-262707	10.18	February 14, 2022
10.18	Investor Rights and Lock-up Agreement.	8-K	001-40440	10.4	June 15, 2022
10.19	Form of Subscription Agreement.	S-4/A	333-262707	10.20	May 10, 2022
10.20	Form Sponsor Support Agreement (included in Exhibit 2.1).	S-4	333-262707	10.21	February 14, 2022
10.21	Form of Company Stockholder Support Agreement (included in Exhibit 2.1).	S-4	333-262707	10.22	February 14, 2022
10.22	Form of Amendment to Company Stockholder Support Agreement entered into on February 12, 2022 by certain stockholders of Senti Biosciences, Inc. (incorporated by reference to and Exhibit 10.1 of Dynamics Special Purpose Corp.'s Current Report on Form 8-K as filed with the SEC on February 15, 2021).	S-4	333-262707	10.24	February 14, 2022
10.23+	Senti Biosciences, Inc. 2022 Inducement Plan and forms of award agreements thereunder.	S-1	333-267390	10.24	September 12, 2022
10.24	ChEF Purchase Agreement, dated as of August 31, 2022, by and between Senti Biosciences, Inc. and Chardan Capital Markets LLC.	8-K	001-40440	10.1	September 1, 2022
10.25	Registration Rights Agreement dated as of August 31, 2022, by and between Senti Biosciences, Inc. and Chardan Capital Markets LLC.	8-K	001-40440	10.2	September 1, 2022

Exhibit Number	Description	Incorporated by Reference			
		Schedule/Form	File No.	Exhibit	Filing Date
10.26+	Non-Employee Director Compensation Policy.	10-Q	001-40440	10.1	November 10, 2022
10.27+	Consulting Agreement between Senti Biosciences, Inc. and David Epstein.	10-Q	001-40440	10.2	November 10, 2022
10.28+	Severance and Change in Control Agreement between the Company and Deborah Knobelman.	10-Q	001-40440	10.3	November 10, 2022
10.29+	Severance and Change in Control Agreement between the Company and Philip Lee.	10-Q	001-40440	10.4	November 10, 2022
10.30+	Severance and Change in Control Agreement between the Company and Tim Lu.	10-Q	001-40440	10.5	November 10, 2022
10.31†	Amendment No. 1 to the Research and License Agreement between Spark Therapeutics, Inc. and Senti Biosciences, Inc., dated December 8, 2022.	10-K	001-40440	10.32	March 22, 2023
10.32†	Side Letter between BlueRock Therapeutics, LP and Senti Biosciences, Inc., dated February 3, 2023.	10-K	001-40440	10.33	March 22, 2023
10.33	Scientific Advisory Board Agreement between Senti Biosciences, Inc. and James Collins.	10-K	001-40440	10.34	March 22, 2023
10.34+	Employee Offer Letter by and between Kanya Rajangam and Senti Biosciences, Inc., dated May 10, 2022.	10-Q	001-40440	10.1	May 9, 2023
10.35†	Amendment No. 2 to the Research and License Agreement between Spark Therapeutics, Inc. and Senti Biosciences, Inc., dated May 12, 2023.	10-Q	001-40440	10.1	August 11, 2023
10.36†	Framework Agreement by and among Senti Biosciences, Inc., GeneFab, LLC and Valere Bio, Inc., dated August 7, 2023.	10-Q	001-40440	10.1	November 14, 2023
10.37†	Seller Economic Share Agreement by and among Senti Biosciences, Inc., GeneFab, Inc and Valere Bio, Inc., dated August 7, 2023.	10-Q	001-40440	10.2	November 14, 2023
10.38†	Development and Manufacturing Services Agreement by and between Senti Biosciences, Inc. and GeneFab, LLC dated August 7, 2023.	10-Q	001-40440	10.3	November 14, 2023
10.39†	Sublease Agreement by and between Senti Biosciences, Inc. and GeneFab, LLC dated August 7, 2023.	10-Q	001-40440	10.4	November 14, 2023
10.40†	Option Agreement by and between Senti Biosciences, Inc. and GeneFab, LLC, dated August 7, 2023.	POS-AM (on S-1)	333-265873	10.8	November 1, 2023
10.41*†	Collaboration and Option Agreement by and between Senti Biosciences, Inc., and Celest Therapeutics (Shanghai) Co. Ltd., dated November 6, 2023.				
16.1	Letter from Marcum LLC to the SEC	8-K	001-40440	16.1	June 15, 2022
21.1	List of Subsidiaries	8-K	001-40440	21.1	June 15, 2022
23.1*	Consent of KPMG LLP				
24.1*	Power of Attorney (included on the signature page to the Annual Report on Form 10-K which forms part of this Annual Report on Form 10-K).				

Exhibit Number	Description	Incorporated by Reference		
		Schedule/Form	File No.	Exhibit
				Filing Date
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), 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			
97*	Senti Biosciences, Inc. Compensation Recovery Policy			
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema 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*	The cover page for the Company's Annual Report on Form 10-K has been formatted in Inline XBRL and contained in Exhibit 101.			

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- * Filed herewith.
 - ** Furnished herewith. This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into
 - ^ Certain exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(b)(2). The Company agrees to furnish supplementally a copy of all omitted exhibits and schedules to the Securities and Exchange Commission upon its request.
 - † Portions of this exhibit (indicated by asterisks) have been omitted because the registrant has determined that the information is both not material and is the type that the registration treats as private or confidential.
 - + Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

SENTI BIOSCIENCES, INC.

By: /s/ Timothy Lu, M.D., Ph.D.

Name: Timothy Lu, M.D., Ph.D.

Title: Chief Executive Officer and President

Date: March 21, 2024

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Timothy Lu and Deborah Knobelman as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the United States Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his/her name.

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

Signature	Title	Date
<u>/s/ Timothy Lu</u> Timothy Lu, M.D., Ph.D.	Chief Executive Officer, President and Director (Principal Executive Officer)	March 21, 2024
<u>/s/ Deborah Knobelman</u> Deborah Knobelman, Ph.D.	Chief Financial Officer and Head of Corporate Development (Principal Financial Officer and Principal Accounting Officer)	March 21, 2024
<u>/s/ Susan Berland</u> Susan Berland	Director	March 21, 2024
<u>/s/ Brenda Cooperstone</u> Brenda Cooperstone	Director	March 21, 2024
<u>/s/ Edward Mathers</u> Edward Mathers	Director	March 21, 2024
<u>/s/ James J. Collins</u> James J. (Jim) Collins	Director	March 21, 2024
<u>/s/ Omid Farokhzad</u> Omid Farokhzad	Director	March 21, 2024



SENTI BIO

EXECUTIVE OFFICERS

Timothy Lu, M.D., Ph.D.
Chief Executive Officer

Yvonne Li, M.B.A.
Interim Chief Financial Officer and
Treasurer

Kanya Rajangam, M.D., Ph.D.
President, Head of Research and
Development and Chief Medical Officer

CORPORATE HEADQUARTERS

Senti Biosciences, Inc.
2 Corporate Drive, First Floor
South San Francisco, CA 94080

STOCK EXCHANGE INFORMATION

Senti Biosciences, Inc. stock is publicly traded
on the Nasdaq Capital Market under the
trading symbol: **SNTI**

ANNUAL MEETING

Senti's annual meeting of stockholders will be
held virtually via the internet, at:

9:00 a.m., Pacific Daylight Time
July 10, 2024
www.virtualshareholdermeeting.com/SNTI2024

INVESTOR RELATIONS CONTACT

Website: <https://investors.sentibio.com/>
Contact: investors@sentibio.com

COMPANY INFORMATION

Please visit our website at
www.sentibio.com for the most recent
company news, earnings, and public
filings with the SEC.

BOARD OF DIRECTORS

Timothy Lu, M.D., Ph.D.
Co-Founder & Chief Executive Officer
Senti Biosciences, Inc.

Susan Berland, M.B.A.
Former Consulting Chief Financial Officer
Bluestar Genomics, Inc.

James J. (Jim) Collins, Ph.D.
Termeer Professor
Massachusetts Institute of Technology

Brenda Cooperstone, M.D.
Former Senior Vice President
Pfizer, Inc.

Omid Farokhzad, M.D.
Chief Executive Officer and Chair of the Board
Seer, Inc.

Edward Mathers
Partner
New Enterprise Associates, Inc.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

KPMG, LLP
55 Second Street, Suite 1400
San Francisco, CA 94105

STOCK TRANSFER AGENT

For shareholder services, please write or call:

Continental Stock
1 State Street, 30th Floor
New York, NY 10004-1561
800-509-5586