UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021
or

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

For the transition period from to
Commission file number: 001-35867

Chimerix, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**33-0903395**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
2505 Meridian Parkway, Suite 100 Durham, North Carolina	**27713**
(Address of Principal Executive Offices)	**(Zip Code)**

(919) 806-1074
(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 $0.001 per share	CMRX	The Nasdaq Global Market

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

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

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

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 x No o

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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 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 o	Accelerated filer o
Non-accelerated filer x	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. o

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on The Nasdaq Global Market on June 30, 2021 was $578,617,872.

The number of outstanding shares of the registrant’s common stock, par value $0.001 per share, as of February 25, 2022 was 87,027,677.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K Part**
Portions of the registrant’s notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after registrant’s fiscal year end of December 31, 2021 are incorporated by reference into Part III of this report……	III

CHIMERIX, INC.
FORM 10-K
For the Fiscal Year Ended December 31, 2021
Table of Contents

PART I

Forward-Looking Statements

This Annual Report on Form 10-K (Annual Report) may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 1A, "Risk Factors" in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events that are subject to risks and uncertainties, may contain words such as "may," "will," "expect," "anticipate," "intend," "plan," "believe," "estimate" or other words indicating future results. Such statements may include, but are not limited to, statements concerning the following:

- the initiation, cost, enrollment, timing, progress and results of our research and development activities, preclinical studies and future clinical trials;
- our ability to obtain and maintain regulatory approval of our current and future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our future product candidates;
- our strategic alliance partners' election to pursue development and commercialization;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our future product candidates;
- the size and growth potential of the markets for our current and future product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our current and future product candidates;
- the rate and degree of market acceptance of our current and future product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or become available;
- the loss of key scientific or management personnel;
- our use of the proceeds from our public offerings; and
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and need for additional financing.

Summary of Risk Factors

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part I, Item 1A of this Annual Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this Annual Report as part of your evaluation of an investment in our common stock.

- We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- While we have received a sole source request from BARDA, there can be no assurances that we will be able to enter into a contract with BARDA on favorable terms, or at all, to act as the sole supplier for the procurement of TEMBEXA for the treatment of smallpox.
- We have only received regulatory approval for TEMBEXA, and all of our other product candidates are still under clinical development and may not obtain regulatory approval or be successfully commercialized.
- We may be unable to obtain, or may be delayed in obtaining, regulatory approval for other most advanced clinical candidates: ONC201 and DSTAT.
- Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates, and even if we generate future revenues, they may not be sufficient to lead to profitability.

- Even though we have obtained regulatory approval for TEMBEXA, or if we obtain regulatory approval for any of our product candidates, including ONC201 and DSTAT, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.
- We rely on third-party manufacturers to produce our preclinical drug supplies, clinical drug supplies and TEMBEXA, and we intend to rely on third parties to produce commercial supplies of any approved product candidates. We rely on limited sources of supply for the drug components for each of our product candidates including, TEMBEXA, ONC201 and DSTAT, and any disruption in the chain of supply for either of these product candidates may cause delays in their development and commercialization.
- We routinely evaluate external assets to build our pipeline of product candidates and there can be no assurance that we will be successful in identifying or completing a transaction for a candidate, that any such transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business. For example, we may experience difficulties in integrating the operations of Oncoceutics into our business and in realizing the expected benefits of the merger with Oncoceutics.
- If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.
- If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, delays in the development of our product candidates, penalties and a loss of business.
- We face risks related to the coronavirus (COVID-19) outbreak, which could significantly disrupt our preclinical studies and clinical trials.

Market, Industry and Other Data

This Annual Report contains estimates, projections and other information concerning our industry, our business and relevant markets, including data regarding the estimated size of relevant markets, patient populations, projected diagnosis rates and the perceptions and preferences of patients and physicians regarding certain therapies, as well as data regarding market research and estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources that we believe to be reliable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph are derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

ITEM 1. BUSINESS

Chimerix Overview

Chimerix is a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. In June 2021, the U.S. Food and Drug Administration (FDA) approved TEMBEXA (brincidofovir) for the treatment of smallpox as a medical countermeasure. Our two most advanced clinical-stage development programs are ONC201 and dociparstat sodium (DSTAT). ONC201 is in development for recurrent H3 K27M-mutant glioma as its lead indication. DSTAT is in Phase 3 development as a potential first-line therapy in combination with standard chemotherapy for the treatment of acute myeloid leukemia (AML).

TEMBEXA (brincidofovir, BCV)

TEMBEXA is a lipid conjugate which acts via inhibition of viral DNA synthesis that is a medical countermeasure for smallpox. On June 4, 2021, the FDA granted TEMBEXA approval for the treatment of smallpox. TEMBEXA is available in tablets and oral suspension. It is approved for adult and pediatric patients, including neonates. TEMBEXA was developed as a medical countermeasure for the treatment of smallpox under a collaboration with Biomedical Advanced Research and Development Authority (BARDA). On July 19, 2021, the FDA confirmed that, following the recent approval, TEMBEXA is entitled to seven years' orphan exclusivity in the United States for the treatment of smallpox beginning with the June 4, 2021 marketing approval. In addition to orphan exclusivity, TEMBEXA patent coverage in the United States is expected to extend into 2034.

TEMBEXA potentially fills an important role as a treatment countermeasure to smallpox; it has a differentiated mechanism of action, a relatively high barrier to resistance and available evidence suggests it can be used in patients who have received the other FDA approved smallpox antiviral treatment. In September, an article was published in the peer review journal, Antiviral Research, providing a thorough assessment of TEMBEXA as a medical counter measure for smallpox.

On December 22, 2021, BARDA issued a Request for Proposal (the "RFP") to Chimerix which confirmed, among other things, BARDA's intent to negotiate a sole source contract with the Company for the development and procurement of a smallpox therapeutic with a mechanism of action distinct from that of TPOXX® (marketed by SIGA Technologies, Inc. ("SIGA")) and with a New Drug Application accepted by the U.S. Food and Drug Administration (the "FDA"). The issuance of the RFP by BARDA is a requisite step in the sole source contracting process and allows the Company to commence negotiations with BARDA and to submit a proposal for a contract with BARDA.

The RFP indicates that BARDA intends to contract with the Company to procure up to 1.7 million treatment courses of a smallpox antiviral. The RFP also requires the Company to perform certain activities to be supported by BARDA, including, but not limited to the execution of a randomized clinical trial in the event of an outbreak, and certain cGMP manufacturing activities. We submitted the proposal to BARDA which is currently under review as a sole source contract, including, but not limited to, provisions concerning price per course of therapy and delivery schedule.

As of December 31, 2021, the Company had completed initial TEMBEXA drug product manufacturing for shipment to the Strategic National Stockpile in response to a potential procurement contract to support national preparedness in the United States.

Oncoceutics Acquisition

In January 2021, we acquired Oncoceutics, Inc. (Oncoceutics), a privately-held, clinical-stage biotechnology company developing imipridones, a novel class of small molecule development-stage compounds. Oncoceutics' lead product candidate, ONC201, is currently in development for recurrent H3 K27M-mutant glioma.

Imipridones and ONC201

Imipridones are a potential new class of selective cancer therapies. These drug candidates target specific G protein-coupled receptors (GPCRs) and mitochondrial caseinolytic protease P (ClpP), in an effort to produce cancer cell death. The imipridone chemical scaffold provides an opportunity to target GPCRs and ClpP with differential specificity and function. This presents an opportunity to develop potential imipridone therapies broadly within cancer and in other diseases as well.

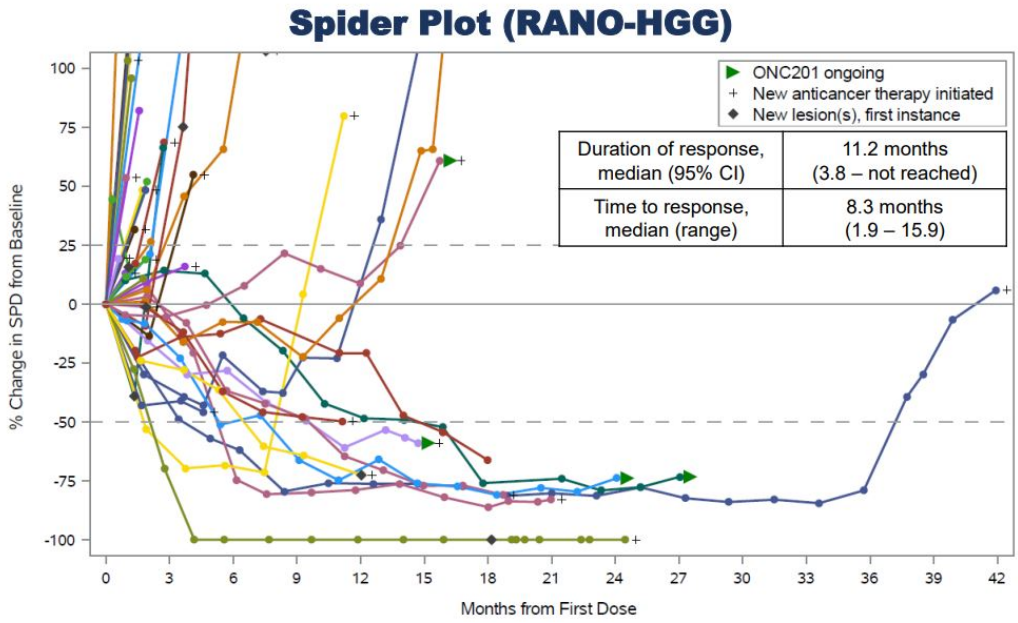
ONC201 selectively targets Dopamine Receptor D2 (DRD2) and ClpP. ONC201 has been shown to selectively induce cell death in cancer cells by binding to and differentially altering activity of DRD2 and ClpP.

Clinical trials of ONC201 in glioma patients with the H3 K27M-mutation are underway at several locations in the U.S. As many as 10% of patients with glioma have the H3 K27M-mutation. The H3 K27M-mutation is found in 50-90% of patients with midline glioma, including 80-90% of children with diffuse intrinsic pontine glioma or DIPG. Currently there is no effective therapy for patients with the H3 K27M-mutation beyond radiation that provides only transient benefit in a fraction of the population. Often it is not possible to resect these tumors when located in the midline structure of the brain and chemotherapy is ineffective. In order to provide context to these results, a review of the literature for comparable survival rates was performed. An analysis of the recurrent diffuse glioma literature indicates an overall survival of 27.5% at 12 months (15 studies; 1,816 patients) and 6.4% at 24 months (10 studies; 1,279 patients). This analysis included studies of ≥30 Grade II-IV glioma patients published after 2009 and was agnostic to molecular profile or tumor location.

Blinded Independent Central Review (BICR) of ONC201 Patient Data

Based on feedback from the FDA, which identified specific patient inclusion criteria designed to isolate the tumor response from ONC201 monotherapy, a blinded independent central review (BICR) efficacy analysis was performed on the first 50 patients meeting the criteria. On November 20, 2021, we reported positive ONC201 data in recurrent H3 K27M-mutant diffuse midline glioma at the Society for Neuro-Oncology Annual meeting.

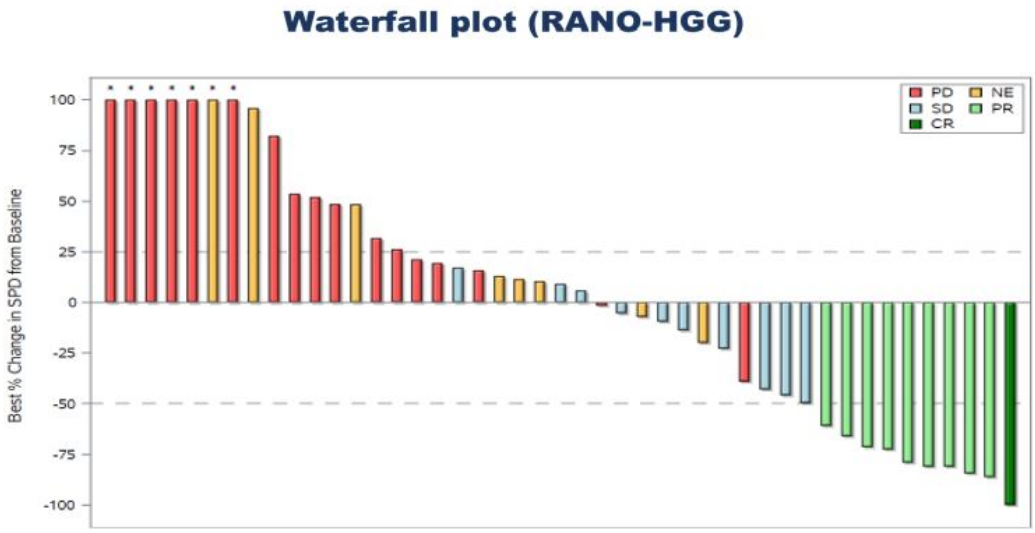
In the spider plot below, each line represents a patient with measurable enhancing lesions per BICR and depicts the percent change in these lesions over time using the sum of products of perpendicular diameters (SPD). Patients whose lesion size decreased shows a decline in the SPD.



- Median duration of response (mDOR) was 11.2 months (95% CI: 3.8 - not reached)
- Median time to response was 8.3 months (range 1.9-15.9)
- Progression-free survival (PFS): 35% (95% CI:21-49%) at 6 months; 30% (95% CI:17-44%) at 12 months

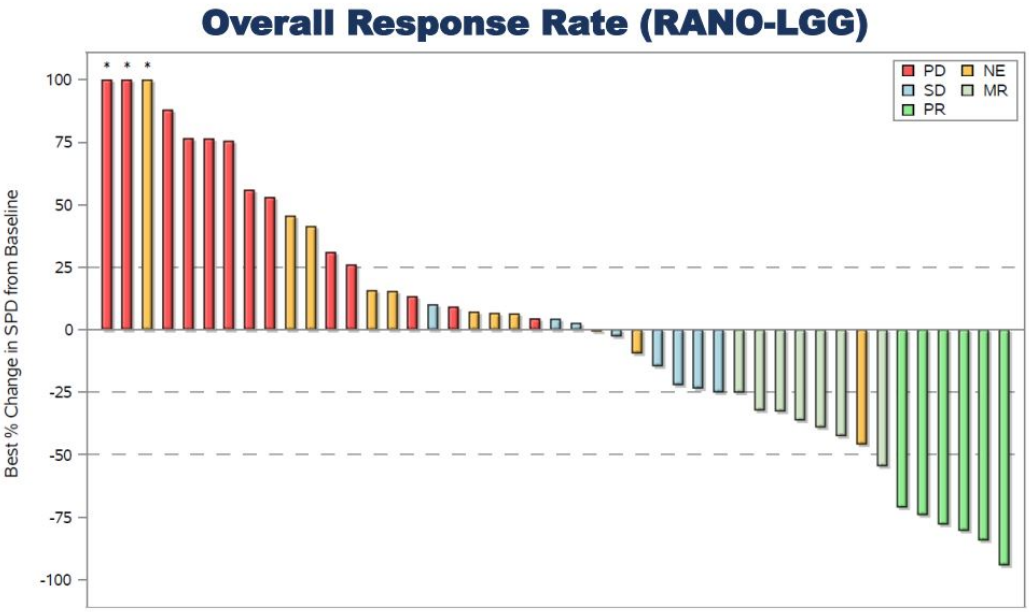
ONC201 monotherapy exhibited durable and clinically meaningful responses in recurrent H3 K27M-mutant diffuse midline glioma (DMG) patients. The Response Assessment in Neuro-Oncology criteria for high grade glioma (RANO-HGG) that quantitatively evaluates neuroimaging with contrast enhancement assessed by dual reader BICR with adjudication determined:

- Overall response rate (ORR) to be 20.0% (95% Confidence Interval (CI): 10.0-34%); including one complete response
- Disease control rate: 40% (95% CI:26-55%)



The Response Assessment in Neuro-Oncology criteria for low grade glioma (RANO-LGG) that quantitatively evaluates neuroimaging without contrast enhancement assessed by dual reader BICR with adjudication determined:

- ORR 26% (95% CI: 15 – 40%)
- Disease control rate: 42% (95% CI:28-57%)



The proportion of patients achieving either a RANO-HGG and/or a RANO-LGG response is 30% (95% CI: 17.9 - 44.6%).

Among evaluable patients (those receiving at least 4mg of dexamethasone daily at baseline), 46.7% achieved at least a 50% confirmed reduction in corticosteroid dose. Among evaluable patients (those with a baseline performance status (KPS/LPS) score of 80 or lower), 20.6% achieved a confirmed improvement, indicative of improved quality of life.

Overall survival:

- 12 months: 57% (95% CI: 41 – 70%)
- 24 months: 35% (95% CI: 21 – 49%)

The cohort was comprised of the first 50 patients enrolled across five ONC201 clinical studies, who met specific criteria designed to isolate the tumor response from ONC201 monotherapy, based on feedback from the FDA. These patients were two years of age or older, had measurable diffuse midline glioma with the H3 K27M-mutation, and had evidence of disease progression following prior therapy with at least radiation completed at least 90 days prior to enrollment.

One serious adverse event, considered to be possibly ONC201-related by the investigator and unlikely to be ONC201-related by the sponsor was identified. Full safety data collection and analysis for this cohort is ongoing. Prior safety review of ONC201 identified the most commonly reported adverse events (AEs) as nausea/vomiting, fatigue and decreased lymphocyte counts.

Chimerix plans to meet with the FDA in the first half of 2022 to review the design for the ONC201 first-line randomized placebo-controlled, Phase 3 trial in combination with radiation therapy that is planned to initiate in the second half of 2022 in patients who harbor the H3 K27M mutation. Under a potential accelerated approval for ONC201 in H3 K27M positive recurrent diffuse midline glioma the FDA may require this trial to be underway at the time of approval. In addition, the Company is conducting a retrospective natural history study, conducting supporting clinical pharmacology studies, completing chemistry, manufacturing and controls (CMC) support and compiling a safety package which it plans to review with the FDA.

In accordance with the terms of the merger agreement between Chimerix and Oncoceutics, the achievement of the 20% overall response rate (ORR) via BICR resulted in a success milestone payment of $20 million to the former Oncoceutics shareholders which was paid in the fourth quarter of 2021.

The FDA has granted ONC201 Fast Track Designation for the treatment of adult recurrent H3 K27M-mutant high-grade glioma, Rare Pediatric Disease Designation for treatment of H3 K27M-mutant glioma, and Orphan Drug Designations for the treatment of glioblastoma and for the treatment of malignant glioma.

In addition to clinical trials in glioma, ONC201 has been evaluated in an open label Phase 2 investigator-initiated study that treated 30 patients at the Cleveland Clinic with rare neuroendocrine tumors. Paraganglioma patients were separated into two cohorts initiating ONC201 either once or twice weekly. A third cohort included patients with other neuroendocrine tumors, including desmoplastic small round cell tumor (DSRCT), dosed weekly with ONC201. The primary endpoint was radiographic response as measured by RECIST criteria. Investigator-assessed data from this study were presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in 2021 and published in the journal *Clinical Cancer Research* in 2022.

In the cohort of paraganglioma patients receiving ONC201 once weekly, 50% (5/10) of patients exhibited a partial response (PR) and two additional patients had stable disease (SD) that lasted longer than three months. Five of the 10 patients in this cohort were treated longer than one year. Among the cohort of paraganglioma patients receiving ONC201 twice weekly 1 PR and 7 SD were observed; this cohort includes 4 of 8 patients who crossed over from the weekly dosing cohort. The third cohort of other neuroendocrine tumors included one PR (DSRCT) and two SD (DSRCT; neuroblastoma) that lasted longer than three months. Importantly, across all cohorts there was no decline in Karnofsky Performance Status (KPS) at week 12 for 93% of patients (28/30) and no dose modification due to treatment-related adverse events.

ONC206

ONC206 is an imipridone, DRD2 antagonist and ClpP agonist that demonstrated enhanced non-competitive DRD2 antagonism relative to ONC201 in preclinical studies and additionally showed disruption of DRD2 homodimers. Treatment of tumor cells with ONC206 elicits a distinct gene expression as compared to ONC201. ONC206 has demonstrated synergistic in vitro activity with ONC201 in cells that have acquired resistance to ONC201. ONC206 showed anti-tumor activity in preclinical models of difficult-to-treat neuroendocrine tumors and high-grade gliomas. In vitro, ONC206 has affected some of the same downstream pathways as ONC201, including activation of the integrated stress response and inhibition of Ras signaling, leading to selective killing of tumor cells.

The first-in-human clinical trial of ONC206 for adults with recurrent primary central nervous system tumors is ongoing at the National Institute of Health (NCT04541082). In addition, the Pediatric Neuro-Oncology Consortium (PNOC), is conducting dose escalating studies.

ONC212

ONC212 is an imipridone, investigational agonist of the orphan GPCR tumor suppressor GPR132, as well as ClpP. Similar to the potential downstream effects of ONC201 and ONC206, in vitro studies of ONC212 demonstrate activation of integrated stress response, inhibition of Ras signaling and selective killing of tumor cells. ONC212 showed broad-spectrum activity across both solid tumors and hematological malignancies, including pancreatic cancer and leukemias prioritized as target clinical indications that exhibit high GPR132 and/or ClpP expression.

Currently ONC212 is in IND-enabling studies. Subject to successful completion of the IND-enabling studies, we expect to conduct first-in-human trials as next steps.

Dociparstat sodium (DSTAT)

In July 2019, we entered into a Development and License Agreement, or the License Agreement, with Cantex Pharmaceuticals (Cantex), pursuant to which we acquired exclusive worldwide rights to develop and commercialize DSTAT for all indications; the planned lead indication is for the first line treatment of acute myeloid leukemia (AML) in combination with cytotoxic chemotherapy. Under the terms of the License Agreement, we are responsible for, and bear the costs of, worldwide development and commercialization of DSTAT. As consideration for the exclusive license, Cantex received an upfront payment of $30.0 million and 10.0 million shares of Chimerix stock. Cantex is also eligible to receive milestone payments up to $202.5 million upon the receipt of product approvals in the United States, the European Union and Japan and sales milestone payments up to $385 million upon achievement of specified net sales levels. We also agreed to pay Cantex tiered royalties based on percentage of net sales beginning at 10% and not to exceed the high teens.

DSTAT for First-Line Acute Myeloid Leukemia (AML)

DSTAT is a novel therapeutic candidate which inhibits the activities of key proteins implicated in the resistance of AML blasts and leukemic stem cells (LSCs) to chemotherapy (e.g., CXCL12, CXCR4, HMGB1, Human Leukocyte Elastase (HLE)). DSTAT also inhibits platelet factor 4 (PF4), which has been demonstrated to play a key role in the maintenance of hematopoietic stem cell (HSC) quiescence and impairment of platelet recovery after chemotherapy.

Collectively, DSTAT's inhibition of these proteins has the potential to benefit patients in three ways:

- Inhibit mechanisms of chemoresistance in AML blasts
- Increase chemosensitivity of leukemic stem cells (LSCs)
- Accelerate platelet recovery following chemotherapy

Preliminary evidence of DSTAT efficacy was demonstrated in a randomized, controlled, Phase 2b, dose-finding study (NCT02873338) evaluating DSTAT in combination with standard 7+3 chemotherapy vs chemotherapy alone in 75 participants ≥60 years of age with newly diagnosed AML. Observed overall survival (OS) was longer in the DSTAT group (median not reached; median follow-up for survivors was 20 months) than the control group (median 11.7 months [95% CI: 7.6, nc]) (observed hazard ratio [HR] 0.68 [95% CI: 0.29, 1.57]). A subset analysis of participants meeting the target inclusion criteria for the planned Phase 3 study demonstrated a favorable observed HR for DSTAT (N=20) vs control (N=19) for OS of 0.51 [95% CI: 0.19, 1.42]. Combination treatment with 7+3 chemotherapy and DSTAT did not show increased toxicity compared with 7+3 chemotherapy alone, nor did it prolong time to platelet or neutrophil recovery.

The improved outcomes seen in patients given DSTAT combined with chemotherapy may be due to DSTAT inhibition of key proteins resulting in sensitization of low abundance resistant AML blasts and quiescent LSCs to cell cycle-dependent

chemotherapies. The potential impact on relapse of a deeper and more durable response to chemotherapy treatment is represented graphically in the figure below.

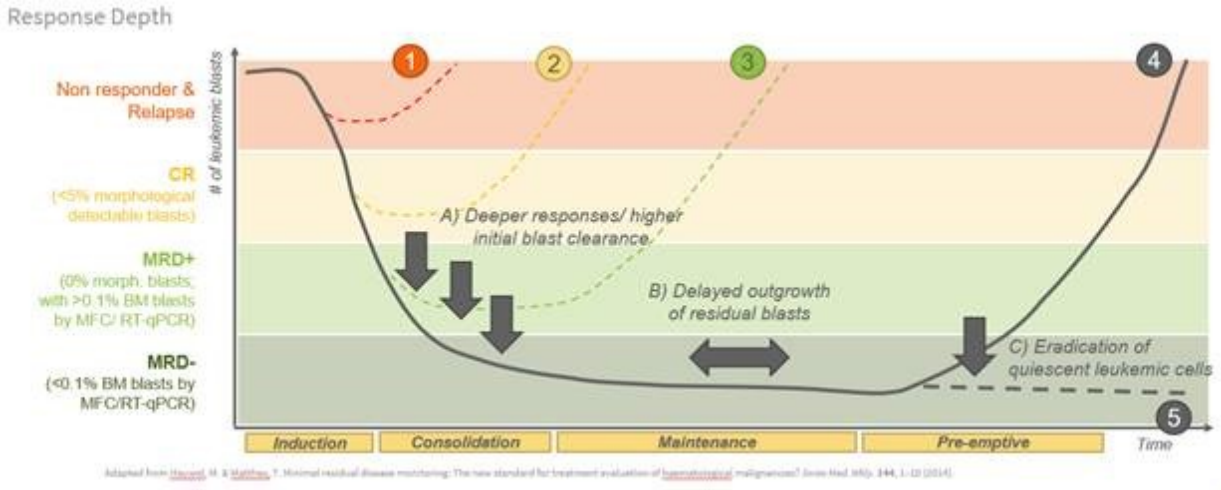


Figure 1: Schematic representation of leukemic cell counts over time. *In the above schematic, hypothetical Patients 2 through 5 are all assumed to achieve a complete response or CR (<5% AML blasts in bone marrow based on morphology); however, their long-term response varies from a relatively quick relapse to a potential cure. Measurable residual disease or MRD is a more sensitive analysis of blasts than CR (e.g., 0.1% cutoff for MRD by flow cytometry is typical vs 5% for CR by morphology)*

The mechanism of action of DSTAT is likely based on the inhibition of multiple proteins involved in chemoresistance and quiescence. This multi-modality may be particularly beneficial in a disease with significant heterogeneity like AML and may provide an advantage relative to other therapies with singular targets (e.g., CXCR4 inhibitors, E-selectin inhibitors).

We believe that DSTAT interaction with the key targets may provide a deeper and more durable response to chemotherapy treatment in AML patients compared to chemotherapy alone, without significant additional toxicity.

In 2020, we conducted an end of Phase 2 meeting with the FDA related to the Company's development of DSTAT in AML. Following the meeting, we incorporated FDA's feedback into the full protocol. We are currently enrolling patients for our 570-subject Phase 3 **D**ociparstat in **A**ML with **S**tandard C**h**emotherapy (DASH AML) study of DSTAT for the treatment of AML.

DASH AML is a randomized, double-blinded trial of approximately 570 newly diagnosed AML patients. The trial includes adult patients who have an intermediate or adverse genetic risk profile. Patients are randomized 1:1 to receive DSTAT in combination with standard cytarabine plus anthracycline (7+3) induction and cytarabine consolidation chemotherapy or will receive standard of care (7+3) induction and consolidation chemotherapy alone. Patients with FLT-3 mutations will be allowed in the study and will be eligible to receive midostaurin.

The primary endpoint of the trial is overall survival (OS). In addition, the FDA has indicated that event-free survival (EFS) using complete response with hematologic recovery to define induction success (CR) may be acceptable as an endpoint for approval. Other endpoints to be evaluated in the trial include: MRD, relapse-free survival (RFS), time to hematologic recovery, and induction response.

In order to supplement the previously reported data from pilot and Phase 2 studies and provide additional evidence regarding DSTAT's potential mechanism of action, the proposed Phase 3 trial includes an early assessment of comparative CR and MRD rates among the first 80 evaluable patients. A recently published meta-analysis of 81 separate studies covering 11,151 patients (Short, et. al., Journal of the American Medical Association Oncology, October 8, 2020) has suggested a link between MRD status and outcomes in patients with AML. Specifically, this large cohort meta-analysis showed that MRD-negative AML patients experience superior 5-year disease-free survival (average hazard ratio: 0.37) and 5-year overall survival (average hazard ratio: 0.36) rates when compared to patients that are MRD-positive. This study suggests that evaluation of MRD status in AML patients may allow for an earlier assessment of therapeutic effects and could lead to acceleration in the development of novel AML therapeutics.

The data from the first 80 evaluable patients of the Phase 3 trial are expected to be unblinded, reported publicly, and available for ongoing analysis of later endpoints, unless the independent Data Monitoring Committee (DMC) determines that exceptional pre-specified thresholds have been achieved, in which case the DMC will have the discretion to maintain blinding, which would allow inclusion of these patients in the final analysis. Enrollment of this study has proceeded more slowly than expected due to hospital staffing shortage related to COVID-19 and the competitive nature of enrolling subjects in this patient population. As such, we do not expect to complete enrollment of the first 80 evaluable patients by year end. We are reviewing a number of options to accelerate the development of DSTAT.

DSTAT has received Orphan Drug and Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of AML.

CMX521 and the Chimerix Antiviral Chemical Library

Chimerix announced acceptance of a Late Breaking Oral presentation of CMX521 at the International Conference of Antiviral Research (ICAR) for March 23rd. Promising preclinical efficacy data generated using CMX521 as a potential prophylactic and treatment of SARS-CoV-2 (COVID-19) infection was generated through a collaboration between Chimerix and the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC). READDI is a global public-private partnership founded at UNC by the UNC Eshelman School of Pharmacy, UNC School of Medicine, Gilling School of Global Public Health, Eshelman Institute for Innovation and the Structural Genomics Consortium. Monotherapy prophylactic administration of aerosol CMX521 every eight hours starting eight hours prior to infection reduced average viral titers in lung on day four post-infection by 3.62 log10 (>99.9% reduction) and prevented weight loss/clinical progression versus placebo. The model used in this study was also used in development of another antiviral therapy that has Emergency Use Authorization for SARS-CoV-2 in the United States. Antiviral efficacy was also demonstrated with monotherapy treatment when CMX521 was initiated post-infection. When administered within 16 hours post-infection, CMX521 significantly reduced SARS-CoV-2 in the lung (Kruskal-Wallis $p<0.0001$) and protected mice from clinical symptoms of disease including weight loss and adverse lung pathology ($p<0.0001$) at day 4 post-infection relative to placebo.

The Chimerix Chemical Library contains over 10,000 heterocyclic ring systems and nucleosides. This library includes approximately 3,500 nucleoside analog compounds, most of which are candidates for lipid conjugation. In a collaboration with the scientists at the University of North Carolina at Chapel Hill (UNC), we continue to evaluate our library of antiviral molecules to identify candidates that may have the potential to accelerate pandemic preparedness or response to SARS-CoV-2 (e.g. COVID-19) or other potential future pandemics.

Our Strategy

The principal components of our business strategy are to:

- **Deliver TEMBEXA, as a medical countermeasure for smallpox, to the U.S. Strategic National Stockpile (SNS) and potentially other markets.** In December 2021, BARDA issued a Request for Proposal (RFP), which confirmed BARDA's intent to negotiate a sole source contract with us for the development and procurement of a smallpox therapeutic with a mechanism of action distinct from that of TPOXX. Currently, our proposal is under review with BARDA regarding this sole source contract.
- **Develop ONC201 for recurrent H3 K27M-mutant glioma.** ONC201 is currently being developed for recurrent H3 K27M-mutant glioma. Data from the potential registrational cohort along with other supportive clinical data from the ONC201 clinical studies, a natural history evaluation, other supporting clinical pharmacology data and chemistry, manufacturing and controls (CMC) support will be compiled for review with the FDA. This data may form the basis for an NDA seeking accelerated approval of ONC201 in the United States.
- **Develop DSTAT for AML.** In 2021 we initiated DASH AML, a Phase 3 trial with a targeted enrollment of approximately 570 patients investigating the use of DSTAT in combination with standard chemotherapy (cytarabine plus anthracycline or “7+3”) in newly diagnosed AML patients. The primary endpoint of the trial is overall survival (OS). The FDA has indicated that event-free survival (EFS) using complete response with hematologic recovery (CR) to define induction success, is acceptable as an endpoint for approval. Other endpoints to be evaluated in the proposed trial include: measurable residual disease (MRD), relapse-free survival (RFS), time to hematologic recovery, and induction response. In order to supplement the previously collected data from the pilot and Phase 2 trials and provide additional evidence of DSTAT’s mechanism of action, the Phase 3 trial includes an early assessment of comparative CR and MRD rates among the first 80 evaluable patients. This data is expected to be unblinded, reported publicly, and available for ongoing analysis of later endpoints. Prior to potential unblinding, this data will be reviewed by an independent DMC. The DMC will have the discretion to

maintain blinding of the data from this early assessment in the event the DSTAT arm shows exceptional advantages to the control arm on CR and MRD, at certain pre-specified thresholds, which would allow inclusion of these patients in the final analysis.

- **Develop ONC206 and ONC212.** We continue to progress development on ONC206 and ONC212. Currently, ONC206 is enrolling in dose escalating clinical trials conducted by the NIH and PNOC. ONC212 data in GLP animal studies is expected in the second half of 2022 and if supportive, we plan to file an IND thereafter.
- **Identify value-creating opportunities from our library of antiviral molecules.** Through a partnership with READDI at UNC, we continue to evaluate our library of antiviral molecules, including CMX521, to identify candidates that may have the potential to accelerate pandemic preparedness or response to SARS-CoV-2 (e.g. COVID-19) or other potential future pandemics.
- **Seek opportunities to in-license other development programs.** We continue to review transactions designed to build our product candidate pipeline, including, but not limited to, merger or acquisition transactions, issuing or transferring shares of common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that this review will result in the identification or consummation of any additional transaction.

Significant Agreements

BARDA

In February 2011, we entered into a contract with the Biomedical Advanced Research and Development Authority (BARDA) for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. BARDA is a division of the U.S. Department of Health and Human Services (DHHS) in the Office of the Assistant Secretary for Preparedness and Response that supports the advanced research and development, manufacturing, acquisition and stockpiling of medical countermeasures. The scope of work for the contract included preclinical, clinical and manufacturing development activities that fell into the following areas: non-clinical animal efficacy studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities.

Under the contract, BARDA reimbursed our costs, plus paid us a fixed fee, for the research and development of brincidofovir as a treatment of smallpox infections. The contract was completed on September 1, 2021 and the contract expired in accordance with its terms. Under the contract, we received $72.5 million in expense reimbursement and $4.6 million in fees.

Pursuant to the contract, Chimerix and the U.S. government share the rights to any inventions that were made in the performance of our work under the contract. Specifically, the U.S. government retains a nonexclusive, nontransferable, irrevocable, paid up license to any invention that was made in the performance of our work under the contract, provided, however, that the U.S. government may, under certain circumstances, including circumstances involving public health and safety, license such inventions to third parties without our consent. There have been no inventions made to date under the BARDA contract.

On December 22, 2021, BARDA issued a RFP, which confirmed, among other things, BARDA's intent to negotiate a sole source contract with the Company for the development and procurement of TEMBEXA. The RFP indicates that BARDA intends to contract with the Company to procure up to 1.7 million treatment courses of a smallpox antiviral.

Before we can enter into a contract we must negotiate its terms, including the price and delivery schedule. In addition, as a governmental agency, BARDA’s ability to enter into a contract is subject to continued funding for this purpose, which can change at any time.

Cantex Pharmaceuticals, Inc.

On July 26, 2019, the Company entered into a License and Development Agreement with Cantex pursuant to which the Company acquired exclusive worldwide rights to develop and commercialize, for any and all uses, a glycosaminoglycan compound known as DSTAT, which is currently being studied for the treatment of acute myeloid leukemia. Under the terms of the license agreement, the Company is responsible for, and bears the costs of, worldwide development and commercialization of DSTAT. In connection with the transaction, Cantex assigned to the Company all of its rights under its DSTAT supply agreements, including its bulk API agreement with Scientific Protein Laboratories LLC (SPL), pursuant to which SPL will exclusively produce DSTAT for the Company through October 2040.

In consideration for the license rights, the Company made an upfront cash payment of $30.0 million to Cantex and issued to Cantex 10.0 million shares of its common stock. For the twelve months ended December 31, 2019, the Company recognized

$65.0 million of acquired in-process research and development expenses for the $30.0 million upfront cash payment, the fair value of the 10.0 million shares of common stock issued to Cantex and $0.1 million of transaction costs. The license agreement obligates the Company to pay Cantex regulatory milestone payments of up to $202.5 million upon receipt of product approvals in the United States, the European Union and Japan, and sales milestone payments of up to $385.0 million upon achievement of specified net sales levels. The Company also agreed to pay Cantex tiered royalties based on percentages of net sales beginning at 10% and not to exceed the high teens.

SymBio Pharmaceuticals

On September 30, 2019, the Company entered into a license agreement with SymBio for the exclusive worldwide rights to develop, manufacture and commercialize BCV for all human indications, excluding the prevention and treatment of orthopoxviruses, including smallpox. Under the terms of the license agreement, SymBio will be responsible for, and bear the future costs of, worldwide development and commercialization of BCV in the licensed indications. Either party may terminate the license agreement upon the occurrence of a material breach by the other party (subject to standard cure periods), or upon certain events involving the bankruptcy or insolvency of the other party. SymBio may also terminate the license agreement without cause on a country-by-country basis upon ninety days' prior notice.

In exchange for the license to certain BCV rights, the Company received an upfront payment of $5.0 million in October of 2019. In addition, the Company is eligible to receive up to $180.0 million in clinical, regulatory and commercial milestones worldwide, as well as low double-digit royalties and additional milestones based on commercial sales. Since entering into the license agreement in September 2019, the Company has recognized all of the $5.0 million of revenue related to the upfront payment. SymBio is currently developing the IV formulation of BCV in an international Phase 2 study in adenovirus.

Merger Agreement with Oncoceutics

On January 7, 2021, we entered into an agreement with the securityholders of Oncoceutics and Fortis Advisors (as securityholders representative) to acquire Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, a novel potential class of compounds. As consideration for the acquisition, we (a) paid an upfront cash payment of approximately $25.0 million, (b) issued an aggregate of 8,723,769 shares of our common stock, (c) issued a promissory note to the representative of the securityholders of Oncoceutics in the principal amount of $14.0 million, to be paid in cash, upon the one year anniversary of the closing of the acquisition, and (d) agreed to make contingent payments up to an aggregate of $360.0 million based on the achievement of certain development, regulatory and commercialization events, as well as additional tiered royalty payments based upon future net sales of ONC201 and ONC206 products, subject to certain reductions, and a contingent payment in the event we receive any proceeds from the sale of a rare pediatric disease priority review voucher based on the Oncoceutics products. We have also passed through to the Oncoceutics securityholders the upfront payment received from China Resources Sanjiu Medical & Pharmaceutical Co., Ltd. pursuant to a license agreement entered into with Oncoceutics prior to the acquisition. The closing payment may be adjusted after the closing, pursuant to procedures, in connection with the finalization of the cash, transaction expenses, debt and working capital amounts at closing. Pursuant to the merger agreement we have certain diligence obligations with respect to further development and commercialization of the Oncoceutics product candidates.

In accordance with the terms of the agreement, the achievement of the 20% ORR via BICR resulted in a success milestone payment of $20 million to the former Oncoceutics shareholders which was paid in the fourth quarter of 2021.

In January 2022, we owed $14.0 million related to the promissory note issued as a part of the agreement and $0.2 million related to closing payment adjustments to the securityholders of Oncoceutics. These amounts were paid net of severance costs due in the amount of $0.6 million and a hold back in the amount of $0.4 million as a reserve against estimated post-closing transaction expenses pursuant to the agreement.

Ohara Pharmaceutical Co.

In 2019, Oncoceutics entered into a license, development and commercialization agreement with Ohara Pharmaceutical Co., Ltd. for ONC201 in Japan. We are entitled to receive up to $2.5 million in nonrefundable regulatory milestone payments, and to tiered royalties based on the aggregate annual net sales of all products, as defined in the agreement, in Japan.

China Resources Sanjiu Medical & Pharmaceutical Co., Ltd. (CR Sanjiu)

In December 2020, Oncoceutics entered into a license, development and commercialization agreement with China Resources Sanjiu Medical & Pharmaceutical Co., Ltd. (CR Sanjiu). Oncoceutics granted CR Sanjiu an exclusive royalty bearing license to develop and commercialize ONC201 in China, Hong Kong, Macau and Taiwan (CR Sanjiu Territory). We are entitled to receive up to $5.0 million in nonrefundable regulatory milestone payments, and to tiered royalties based on the aggregate annual net sales of all licensed products, as defined in the agreement, in the CR Sanjiu Territory.

Commercial Operations

In June 2021, we received FDA approval of both TEMBEXA tablet and suspension for the treatment of smallpox. The U.S. government is the largest source of development and procurement funding for academic and biopharmaceutical companies contracting biodefense research or developing vaccines, anti-infectives and immunotherapies directed at potential agents of bioterror or biowarfare. U.S. government spending on biodefense programs includes development funding awarded by the National Institute of Allergy and Infectious Diseases, BARDA and the Department of Defense (DoD), and procurement of countermeasures by BARDA, the Centers for Disease Control and Prevention and the DoD. In addition to the U.S. government, we believe that potential additional markets for the sale of biodefense countermeasures include:

- foreign governments, including both defense and public health agencies;
- non-governmental organizations and multinational companies, including transportation and security companies;
- healthcare providers, including hospitals and clinics; and
- state and local governments, which may be interested in these products to protect, among others, emergency responders, such as police, fire and emergency medical personnel.

The U.S. FDA approval of TEMBEXA does not allow for sale beyond the U.S. Strategic National Stockpile. We will likely need to meet additional regulatory requirements before sales can be made in the U.S. beyond the Strategic National Stockpile.

If ONC201 is approved for recurrent H3 K27M-mutant glioma and/or DSTAT is approved for the treatment of AML, we believe it is possible for us to commercialize ONC201 and DSTAT in the United States. We anticipate that commercialization of one or both products would entail a relatively small commercial infrastructure, which may include a contract sales force, partner sales force, or an internally developed commercial organization.

Outside of the United States, subject to obtaining necessary marketing approvals, we may seek to commercialize ONC201 and DSTAT ourselves or through distribution or other collaboration arrangements. If we elect to develop ONC201 for other indications and if DSTAT is also developed for other indications, we would plan to do so selectively either on our own or by establishing alliances with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs, reimbursement complexities and our available resources.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our therapeutic experience, scientific and commercial knowledge provide us with competitive advantages, we will face competition from large and small pharmaceutical and biotechnology companies, including specialty pharmaceutical and generic drug companies, and other emerging technologies.

We believe that the key competitive factors that will affect the commercial success of TEMBEXA, ONC201, DSTAT and our other product candidates are the efficacy, safety and tolerability profile and the risk-benefit trade-off compared to alternative therapies or procedures. Securing market access and reimbursement will be an important element of product uptake and market penetration. Our commercial opportunity could be negatively impacted if our competitors develop or market products or other technologies that are more effective, better tolerated, safer, more convenient or have greater market access than TEMBEXA, ONC201 or DSTAT, or obtain regulatory approval for their products more rapidly than we do. In addition, our ability to compete will be affected by the availability of generic products.

ONC201 is the most clinically advanced program in the industry for potentially treating tumors which harbor the H3 K27M mutation. If approved, treatment with ONC201 is expected to be targeted to patients whose tumor harbors the H3 K27M mutation. There are currently no commercially available treatments that target the H3 K27M mutant patient population.

If approved, ONC201 could compete with a number of existing products, new products in development and possible combination therapies used for brain cancers including generic drugs such as chemotherapy, targeted agents, immunotherapies,

and other therapies. Select products that are currently used, or being developed for use, to treat brain cancers include, but are not limited to:

- Systemic therapies approved to treat brain cancer: temozolomide, lomustine, carmustine, everolimus, and bevacizumab;
- Tumor-treating fields such as Optune®; and
- Other investigational agents for the treatment of brain cancer: immunotherapies (CAR-T, durvalumab, VBI-1901, etc), viral therapies (DCVax-L, etc.), targeted agents (panobinostat, paxalisib, MDNA55) and other therapies

If approved, DSTAT would compete with a number of existing products, new products in development and other types of combination therapies in development for first line AML including generic drugs such as standard 7+3 (cytarabine plus anthracycline) chemotherapy, alternative non-chemo based therapy regimens and other 7+3 combination therapies that target specific mutations. Select products that are currently used, or being developed for use, to treat AML include but are not limited to:

- Standard 7+3 (cytarabine plus anthracycline) with or without targeted agents (including but not limited to the experimental treatment uproleselan, Mylotarg®, IDH1 and IDH2 inhibitors (enasidenib and ivosidenib), FLT-3 inhibitors (midostaurin and gilteritinib), and other targeted agents such as gemtuzumab, glasdegib, and venetoclax);
- Vyxeos® and combinations with Vyxeos;
- Hypomethylating agents or low dose cytarabine with or without venetoclax; and
- Other consolidation and maintenance therapies (including hypomethylating agents, venetoclax, and stem cell transplantation).

Clinical trials with these alternatives have the potential to compete for and thus slow enrollment in the DSTAT clinical development program, with resulting impacts on the time to Phase 3 results (and thus time to market). Competition for patients and/or evolutions in the standard of care could render the completion of Phase 3 clinical development not feasible. Even if DSTAT clinical trials are successful, we anticipate that we will face intense and increasing competition as new products enter the market, as advanced technologies become available and as increasing numbers of generic formulations of currently branded products become available.

Changes in the health care system may limit our ability to price TEMBEXA, ONC201, DSTAT and our other product candidates at a level that would allow recovery of our research and development costs and may impede our ability to generate or maintain a profit.

We believe that TEMBEXA, ONC201, and DSTAT have potential benefits over existing and potential competitive products as described in more detail under “Business - TEMBEXA”, “Business - ONC201” and “Business - Dociparstat sodium”, respectively. As a result, we believe that these products should be well positioned to gain adoption if we obtain the required regulatory approvals. However, even with those benefits, we may not be able to make promotional claims that these products are superior to competing products without conducting additional studies, which delivers differentiated data. See “Risk Factors - Risks Related to Commercialization of Our Product Candidates.”

Our Intellectual Property

We strive to protect and enhance the proprietary technologies we believe are important to our business, including by seeking and maintaining patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain licenses to our intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Antiviral Patent Portfolio

At February 15, 2022, our worldwide antiviral patent portfolio included:

- 80 patents or patent applications that we own or have in-licensed from academic institutions, related to brincidofovir, and other antivirals, which represented a increase over the number of patents in our patent portfolio at the end of fiscal year 2020;
- This includes 55 US and foreign exclusively and jointly owned patents and 25 US and foreign applications related to brincidofovir, and other antivirals. Granted European and Eurasian patents are counted as one patent and have been validated throughout Europe and Eurasia, respectively;
- Five jointly-owned patents US and foreign patents and seven jointly-owned US patent applications related to our agreement with UM regarding our proprietary Chemical Library; and
- One US patent, one US patent application and one European patent application exclusively owned by Chimerix directed to a morphic form of a compound from the Chemical Library.

In 2015, U.S. Patent No. 8,962,829 covering a method of synthesis and the commercial morphic form of brincidofovir was issued to Chimerix. With the addition of this patent, composition of matter coverage for brincidofovir in the U.S. is expected to extend to October 2034, excluding any additional term from patent term adjustments or patent term extensions.

DSTAT Patent Portfolio

- 64 patents or patent applications that we own or have in-licensed from Cantex, related to DSTAT;
- This includes 49 US and foreign issued patents and 15 pending US and foreign applications related to DSTAT;
- Patent protection for DSTAT is expected to extend through 2033, with the potential for 2038 in the U.S. in the event of full patent term restoration.

Oncoceutics Patent Portfolio

- 404 patents or patent applications related to imipridones that we have acquired rights to through our merger with Oncoceutics, Inc. (owned or in-licensed by Oncoceutics);
- This includes 194 US and foreign issued patents and 72 pending US and foreign applications related to ONC201;
- Patent protection for ONC201's lead indication is expected to extend into 2037 in the U.S., with the potential for 2042 in the U.S. in the event of full patent term restoration.

Patents generally have a term of twenty years from the date they are filed. As our patent portfolio has been built over time, the remaining terms of the individual patents across our patent portfolio vary. We believe that our patents and patent applications are important for maintaining the competitive differentiation of our lipid-antiviral-conjugate technology platform and the Chimerix Chemical Library, enhancing our freedom of action to sell our antivirals, upon appropriate regulatory approvals, in markets in which we choose to participate, and maximizing our return on research and development investments. No single patent is in itself essential to the conduct of our business as a whole.

We also seek to expand our intellectual property portfolio through licensing intellectual property from third parties as we deem appropriate. We have granted, and will continue to grant to others, licenses under our patents when we consider these arrangements to be in our interest.

Manufacturing

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. In the past, we have relied on third-party manufacturers for supply of our approved product, TEMBEXA, and our product candidates, ONC201 and DSTAT, as well as our other product candidates.

We expect that in the future we will rely on such manufacturers for supply of drug substance and drug product that will be used in clinical trials of DSTAT, our expanded access program for ONC201 and other clinical trials as well as for commercial purposes should ONC201 or DSTAT be approved. In July 2019, we were assigned Cantex’s rights under a supply agreement with Scientific Protein Labs (SPL) pursuant to which SPL will exclusively produce DSTAT drug substance for us through October 2040 (the Supply Agreement). We have agreed that SPL will be our exclusive provider of DSTAT during the term of the Supply Agreement. In addition, in July 2019 we were assigned Cantex’s rights under a supply agreement with Pyramid Laboratories Inc. (Pyramid) pursuant to which Pyramid will provide DSTAT finished drug product to us. When produced on a commercial scale, we expect that cost-of-goods-sold relating to ONC201, DSTAT and TEMBEXA will generally be in-line

with that of other targeted oncology therapies, heparin-derived molecules and small-molecule pharmaceutical compounds, respectively.

The manufacturing process for TEMBEXA drug substance is relatively straight-forward and generally in-line with other small molecule pharmaceutical compounds in terms of cost and complexity. The process is robust and reproducible, does not require dedicated reactors or specialized equipment, uses common synthetic chemistry and readily available materials, including off-the-shelf and made-to-order starting materials, and is readily transferable.

Our current drug substance supply chain for TEMBEXA involves various contractors that supply the raw materials for the drug substance process, a contract manufacturer for an intermediate, and a contract manufacturer for the drug substance. We have a validated large-scale drug substance manufacturing process at our selected contractor that will produce the potential procurement supply of drug substance. Manufacturers of drug components must meet certain FDA qualifications with respect to manufacturing standards. At present, we have qualified only one firm as a supplier of drug substance. We continually assess our manufacturing needs and may seek to engage additional qualified vendors as circumstances dictate. Changes in our requirements may require revalidation of the manufacturing process at a different scale and potentially at a different contractor depending on the necessary scale, infrastructure and technical capabilities. To ensure continuity in our supply chain, we plan to establish supply arrangements with alternative suppliers for certain portions of our supply chain, as appropriate.

Our TEMBEXA drug products (tablets and oral suspension) are also manufactured by contract development and manufacturing organizations (CDMOs). The CDMOs must meet certain FDA qualifications with respect to manufacturing standards. Manufacturers for each product have been selected and qualified with registration and validation batches to support NDA marketing applications with the FDA. In addition, scale up of suspension products is planned in 2022 and will produce potential procurement supplies. The tablet process has already been scaled up to meet potential procurement demand.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our systems and contractors are required to be in compliance with these regulations, and this is assessed regularly through monitoring of performance and a formal audit program. We have personnel with extensive technical, manufacturing, analytical and quality experience and strong project management discipline to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and government authorities of member states of the EU and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any product candidate that we develop must be approved by the FDA or EMA before it may be legally marketed in the United States or EU and in other countries by the responsible national regulatory agency before it may be legally marketed.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA), and implementing regulations. Drugs are also subject to other federal, state and local statutes and 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. Failure to comply with the applicable U.S. requirements at any time during the product development process, FDA approval process or after FDA approval, may subject an applicant to administrative or judicial civil or criminal sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, debarment, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action, whether before or after the FDA approval process, could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies according to good laboratory practices (GLP), or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as current good clinical practices (GCPs), to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice standards (cGMP), to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA inspection of the nonclinical and clinical trial sites that generated the data in support of the NDA; and FDA review of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the drug 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 drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy subjects or affected patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Patients not meeting protocol inclusion and exclusion criteria may be considered for our expanded access program under the IND. Clinical trials must be conducted in accordance with the FDA's regulations comprising the good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board (IRB), at or servicing each institution at which the clinical trial will be conducted. 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 form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, 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 drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board

may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as 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 drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act (PREA), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The FDA reviews all NDAs submitted to determine if they are substantially complete before it accepts them for filing; this initial review period prior to accepting the NDA for filing is 2 months in duration. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has 10 months from the date of accepting the NDA for filing in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission without prior agreement reached at a pre-submission meeting.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy (REMS), is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements. If major issues with trial conduct are identified at a site, data collected from that site can be determined to be unacceptable for supporting the application. 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.

The NDA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The

FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials testing, which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

U.S. Orphan Drug Designation

Our investigational agent, ONC201 has been granted an orphan drug designation for the treatment of glioblastoma and for the treatment of malignant glioma. DSTAT also has orphan drug designation for the treatment of AML. In addition, BCV has been granted orphan drug designation for the treatment of smallpox. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition 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 to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, 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 a product for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if a drug candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Expedited Development and Review Programs

The FDA has a number of programs that are intended to expedite or facilitate the process for reviewing new drugs and biological products for serious conditions that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track, Breakthrough Therapy, and/or Priority Review designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Our investigational agents, ONC201 and DSTAT, have been granted Fast Track designation.

Breakthrough Therapy designation is for a drug that is intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.

Unique to Fast Track and Breakthrough Therapy products, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing approval, including Fast Track and Breakthrough Therapy programs, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product 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 drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to establish safety and efficacy for the approved indication. In addition, the FDA currently requires as a condition for accelerated approval pre-review of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track, Breakthrough, and Priority Review designations and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any drug products for which we or our strategic alliance partners receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising agreements include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Our strategic alliance partners may also utilize third parties for some or all of a product we are developing with such strategic alliance partner. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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 and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our drug candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

FDA Regulation of Companion Diagnostics

ONC201 requires a diagnostic test to identify patients with H3 K27M-mutant glioma. In clinical trials, this mutation is being detected by Laboratory Developed Tests regulated under the Clinical Laboratory Improvement Amendments. In order to obtain NDA approval of ONC201, we or a collaborator will need to obtain FDA approval of an in vitro companion diagnostic for use in selecting patients with the mutation. If safe and effective use of a therapeutic product depends on an *in vitro* diagnostic, or IVD, the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product in order to allow for its commercial use.

US Health Care Laws

Our operations may be subject to federal and state health care laws and regulations including, without limitation: anti-kickback statutes, false claims statutes, patient data privacy and security laws, and health care professional payment transparency laws and regulations, many of which may become more applicable if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of these laws or regulations, we may be subject to penalties, including significant administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal healthcare programs, and 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, as well as contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations.

Reimbursement / Health Reform

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payers include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including prescription drugs. In addition, significant uncertainty exists as to the reimbursement status of newly approved prescription drugs and other healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of any of our products that is successfully developed and approved. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payers. Reimbursement may not be available or sufficient to allow the sale of any of our products that is successfully developed and approved on a competitive and profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities to provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not

required to pay for all covered Part D drugs, and each Part D prescription drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all of the drugs within each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

Government payment for some of the costs of prescription drugs may increase demand for any of our products that is successfully developed and approved. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, although the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Accordingly, any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. Currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress may in the future consider legislation that would lift the ban on federal negotiations.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research would be developed by the U.S. Department of Health and Human Services (DHHS), Agency for Healthcare Research and Quality and the National Institutes of Health, and periodic reports on the status of the research and related expenditures would be made to the U.S. Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear whether research would have any effect on the sales of any of our products that are successfully developed and approved, if the product or the condition that it is intended to treat becomes the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits of a competitor’s product could adversely affect the sales of any of our products that is successfully developed and approved. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, ACA), has had a significant impact on the health care industry. The ACA was enacted in an effort to expand coverage for the uninsured while at the same time containing overall healthcare costs. Among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program. However, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. The ACA may be subject to additional judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact ACA.

If not preempted by the ACA, several states and local jurisdictions require pharmaceutical manufacturers to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in

the states. Other states prohibit providing various other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, some states, such as California, Nevada and Massachusetts, require pharmaceutical manufacturers to implement compliance programs or marketing codes. In addition, certain states and local jurisdictions require registration of pharmaceutical sales representatives. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

There has also been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, including several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, increase drug pricing transparency, reduce the cost of drugs under Medicare, review relationships between pricing and manufacturer patient assistance programs, and reform government program drug reimbursement methodologies. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule and guidance in September 2022, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Such reform efforts are likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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 EU provides options for its member states to restrict the range of medicinal products for which their respective national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 products for which we receive marketing approval. Historically, the price structures for products launched in the EU do not follow those of the United States and tend to be significantly lower.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we and our strategic alliance partners will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we or our collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application (CTA), must be submitted.

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

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we or our strategic alliance partners must submit a marketing authorization application. The application used to file the NDA or a Biologics License Application in the United States is similar to the application dossier (eCTD) required in the EU.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials 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 or our strategic alliance partners 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.

EU Review and Approval Process

In the EU, there are two main routes for authorizing the marketing of medicines, a centralized route and a national route. The centralized procedure is compulsory for certain types of medicinal products which are produced by biotechnology processes, advanced therapy medicinal products and for those which are designated as orphan medicinal products. Besides the products falling under the mandatory scope, the centralized procedure is also optional for medicinal products that constitute a significant therapeutic, scientific or technical innovation i.e. new active substances or other medicinal products that constitute a significant therapeutic, scientific or technical innovation, that contain an active substance not authorized in the European Union before May 20, 2004 or for which a centralized procedure would be in the interest of patients.

Under the centralized authorization procedure, pharmaceutical companies submit a single marketing-authorization application to the EMA. EMA's Committee for Medicinal Products for Human Use (CHMP) carries out a scientific assessment of the application and makes a recommendation to the European Commission whether the medicine should be marketed or not. If authorization is granted by the European Commission, the centralized marketing authorization is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

Additionally, medicines that belong to at least one of the below categories may be granted a conditional market authorization (CMA).

A CMA may be granted if: (1) the CHMP finds that the benefit-risk balance of the product is positive, (2) it is likely that the applicant will be able to provide comprehensive data, (3) the unmet medical needs will be fulfilled, and (4) the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to need for further data.

CMAs are valid for one year and can be renewed annually. The CMA holder will be required to complete specific obligations (to complete ongoing or new studies, and in some cases additional activities) with a view to providing comprehensive data confirming that the benefit-risk balance is positive. Once comprehensive data on the product have been obtained, the CMA may be converted into a full marketing authorization (not subject to specific obligations). Initially, this is valid for five years, but can be renewed for unlimited validity.

Orphan Designation in the EU

In order to qualify for Orphan Designation, a medicine must meet the following criteria:

- it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating;
- the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

EMA is responsible for reviewing applications from sponsors for orphan designation. The EMA's Committee for Orphan Medicinal Products (COMP), through its network of experts, examines applications for Orphan Designation and issues an

opinion to EMA. The evaluation process takes approximately of 90 days from validation. Once EMA receives COMP's opinion, EMA sends it to the European Commission, which is responsible for granting the Orphan Designation.

At the time a sponsor of a marketing application files for marketing authorization for a medicine that has received Orphan Designation, the sponsor must also submit a report on the maintenance of the Orphan Designation in parallel. EMA uses this report to determine whether the medicine can maintain its status as an orphan medicine and benefit from the extended market exclusivity applicable to orphan products. Market exclusivity is linked to the maintenance of the Orphan Designation when the medicine receives a marketing authorization for the indication concerned.

If it is determined that a medicine still meets the criteria for Orphan Designation at the time of marketing approval, that medicine may benefit from a period of ten years market exclusivity in the EU. This incentive is intended to protect orphan medicines from market competition with similar medicines with similar indications once they are approved, and fundamentally to encourage the development of medicines for rare diseases.

The applicant is obliged to submit an annual report to the EMA every year after their medicine has been granted orphan designation. The annual report needs provide information on the status of the development of the medicine, such as a review of ongoing clinical studies, a description of the investigation plan for the coming year and any anticipated or current problems in the process, difficulties in testing and potential changes that may have an impact on the medicine's orphan designation.

The European Commission is responsible for granting market exclusivity for orphan medicines. Market exclusivity is linked to each specific Orphan Designation for which a marketing authorization has been granted.

The period of market exclusivity is extended by two years for medicines that also have complied with an agreed pediatric investigation plan (PIP). Each orphan designation for a product linked to a separate orphan condition is eligible for a two-year extension if this is accounted for in the PIP. The extension is granted by the European Commission based on the positive compliance check from the Pediatric Committee and opinion from the CHMP.

Environmental, Health and Safety Regulations

We are subject to various environmental, health and safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous substances. From time to time, and in the future, our operations may involve the use of hazardous materials.

Employees and Human Capital Resources

As of December 31, 2021, we had 87 full-time employees. Of these employees, 68 employees are engaged in research and development activities and 19 employees are engaged in finance, legal, human resources, facilities and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We expect to continue to add additional employees in 2022 with a focus on expanding our expertise and bandwidth in clinical and preclinical research and development. We continually evaluate our business needs and opportunities and balance in house expertise and capacity with external expertise and capacity. Currently, we rely on third-party contract manufacturers.

Our Culture. The success of our human capital management investments is evidenced by our low employee turnover, a number which is periodically reviewed by our Board of Directors as part of their oversight of our human capital strategy.

Employee Engagement, Talent Development & Benefits. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, flexible working arrangements, including work-from-home arrangements, retirement planning and paid time off. As part of our promotion and retention efforts, we also invest in ongoing leadership development through programs as well as offer tuition reimbursement.

Diversity & Inclusion. Pursuing diversity in all forms, because diversity makes us better, is one of our Corporate Values. Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

Corporate Information

We were incorporated in the State of Delaware in April 2000. Our corporate headquarters are located at 2505 Meridian Parkway, Suite 100, Durham, North Carolina 27713 in a facility we lease encompassing approximately 21,325 square feet of office space. The leases for this facility expire in July 2026. We separately lease laboratory space in Durham, North Carolina, encompassing a total of approximately 7,925 square feet. The lease for this laboratory space in Durham expires in July 2026. Through our subsidiary, Oncoceutics, Inc., we lease month to month approximately 375 square feet of office space in Philadelphia, Pennsylvania.

Our corporate website address is www.chimerix.com. Our filings with the Securities and Exchange Commission are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. The information contained on, or that can be accessed through, our website is not part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

ITEM 1A. RISK FACTORS

Except for the historical information contained herein or incorporated by reference, this Annual Report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our research, development and commercialization efforts, our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference into this Annual Report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Condition and Need For Additional Capital

We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.

We are a biopharmaceutical company focused primarily on developing and commercializing TEMBEXA for the treatment of smallpox, ONC201 for the treatment of recurrent H3 K27M-mutant glioma and dociparstat (DSTAT) for the treatment of acute myeloid leukemia (AML). We have incurred significant net losses in each year since our inception, including net losses of $173.2 million, $43.5 million and $112.6 million for the twelve months ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of approximately $885.6 million.

To date, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, through government funding, licensing fees and debt. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We may continue to incur losses and negative cash flows for the foreseeable future. The size of any loss will depend, in part, on the rate of future expenditures and our ability to generate revenues. In particular, we expect to incur substantial expenses as we seek to:

- continue development and manufacturing activities related to imipridones, including ONC201 for the treatment of recurrent H3 K27M-mutant glioma, and other potential indications;
- continue development and manufacturing activities related to DSTAT for the treatment of AML and other potential indications;
- Enter into an agreement with BARDA to sell TEMBEXA into the U.S. Strategic National Stockpile as a medical countermeasure for the treatment of smallpox;
- obtain regulatory approvals for ONC201 and DSTAT;
- scale-up manufacturing capabilities to commercialize TEMBEXA and in the event we receive regulatory approval, ONC201 and DSTAT;
- identify and in-license additional product candidates to expand our research and development pipeline;
- maintain, expand and protect our intellectual property portfolio; and
- continue our internal research and development efforts and seek to discover additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including acquiring or discovering product candidates, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities.

To date, we have only obtained regulatory approval for TEMBEXA, and none of our product candidates have been commercialized. We may not succeed in developing additional product candidates or commercializing any product candidate. If

we do not successfully develop or commercialize any product candidate, or if revenues from any products that do receive regulatory approvals are insufficient, we will not achieve profitability and our business may fail. In addition to these risks in the United States, assuming regulatory approval in other geographies, our revenues are also dependent upon the size of markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success outside of the United States.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates, and even if we generate future revenues, they may not be sufficient to lead to profitability.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for and commercialize product candidates. We may not generate revenues from product sales for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our success in:

- reaching agreement with BARDA for the procurement of TEMBEXA on financial terms consistent with management's expectations, or at all;
- obtaining favorable results for and advancing development of imipridones, including ONC201 for the treatment of recurrent H3 K27M-mutant glioma, and other potential indications;
- obtaining favorable results for and advancing the development of DSTAT for the treatment of AML;
- obtaining United States regulatory approval(s) for ONC201 and DSTAT;
- obtaining foreign regulatory approval(s) for TEMBEXA, ONC201 and DSTAT;
- generating, licensing or otherwise acquiring a pipeline of product candidates which progress to clinical development, regulatory approval, and commercialization.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and achieve product sales. Our anticipated development costs would likely increase if we do not obtain favorable results or if development of any product candidate is delayed. In particular, we would likely incur higher costs than we currently anticipate if development of any product candidate is delayed because we are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate, or we decide to conduct additional studies or trials for strategic reasons.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict with certainty the timing or amount of any increase in our anticipated development costs that will result should any additional trials be necessary.

In addition, TEMBEXA, or any product candidate if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that may not be commercially available for a number of years, if at all. For any approved product candidate, we anticipate incurring significant costs in connection with commercialization. As a result, we cannot assure you that we will be able to generate revenues from sales of any approved product candidate, or that we will achieve or maintain profitability even if we do generate sales.

If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs, seek corporate partners for the development of our product development programs or relinquish or license on unfavorable terms, our rights to technologies or product candidates.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We believe that our existing capital available to fund operations will enable us to fund our current operating expenses and capital requirements for at least the next twelve months. Changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate, and our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expected, or because the FDA or foreign regulatory authorities require us to perform studies or trials in addition to those that we currently anticipate.

In July 2019, we entered into a License and Development Agreement with Cantex in which we acquired an exclusive worldwide license to develop and commercialize DSTAT. We are currently enrolling a Phase 3 trial in AML.

In January 2021, we acquired Oncoceutics, Inc. (Oncoceutics), a privately-held, clinical-stage biotechnology company developing imipridones, a novel potential class of compounds. Oncoceutics' lead product candidate, ONC201, is currently being evaluated in multiple clinical studies including in a registrational program for recurrent H3 K27M-mutant glioma.

We are also pursuing additional external opportunities to build our pipeline of product candidates, and we may need to raise additional funds if we identify additional product candidates, which we may obtain through one or more equity offerings, debt financings, government or other third-party funding, strategic alliances and licensing or collaboration arrangements.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our most advanced clinical compounds, or any other product candidate. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of TEMBEXA, ONC201, DSTAT, or any other product candidate;
- seek corporate partners for TEMBEXA, ONC201, DSTAT, or any other product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects and on our ability to develop our product candidates.

If we draw down on our credit facility with Silicon Valley Bank, the terms of our loan and security agreement place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our securities to decline.

Our $50.0 million revolving credit facility with Silicon Valley Bank is secured by a first priority perfected security interest in substantially all of our assets other than our intellectual property, subject to certain exceptions.

Our loan agreement with Silicon Valley Bank requires us to comply with certain financial covenants, including requiring that we maintain specified liquidity and cash levels at certain times. The loan agreement also requires us to comply with a number of other covenants (affirmative and negative), including restrictive covenants that limit our ability to, among other things, incur additional indebtedness; merge or consolidate with or into any other organization or otherwise suffer a change in control; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; and transfer a material portion of our assets, in each case subject to exceptions.

In addition to other specified events of default, and subject to limited exceptions, Silicon Valley Bank could declare an event of default upon our non-compliance with certain covenants or the occurrence of certain events that it may determine, in its sole discretion, to have a material adverse effect, including: a material adverse change in, or a material adverse effect on our business, property, assets or operations, taken as a whole; a material impairment of our ability to perform any of our obligations under the loan agreement; a material adverse effect upon the collateral for the loan or its value; or a material impairment of the enforceability or priority of the liens upon the collateral for the loan or the legality, validity, binding effect or enforceability of the loan agreement or related agreements.

If we default under the credit facility, Silicon Valley Bank may accelerate all of our repayment obligations, which may require us to seek additional or alternate financing and/or modify our operational plans. We cannot guarantee that we will be able to comply with all of the covenants contained in the Silicon Valley Bank loan agreement in the future, or secure waivers if or when required. If we are unable to comply with or obtain a waiver of any noncompliance under the loan agreement, Silicon Valley Bank could declare an event of default or require us to further renegotiate the loan agreement on terms that may be significantly less favorable to us, or we may be required to seek additional or alternative financing. If we were to seek additional or alternative financing, any such financing may not be available to us on commercially reasonable terms or at all. If we are unable to access funds to meet those obligations or to renegotiate our agreement, Silicon Valley Bank could foreclose on

our pledged assets and we would have to immediately cease operations. In addition, during the continuance of an event of default, the then-applicable interest rate on the then-outstanding principal balance is subject to increase. Upon an event of default, Silicon Valley Bank could also require us to repay the loan immediately, together with a prepayment penalty, and other fees. If we were to renegotiate the agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, Silicon Valley Bank's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Silicon Valley Bank of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our securities to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness. If we are unable to repay, refinance or restructure our indebtedness when payment is due, Silicon Valley Bank could proceed against the collateral or force us into bankruptcy or liquidation.

We routinely evaluate external assets to build our pipeline of product candidates and there can be no assurance that we will be successful in identifying or completing a transaction for a candidate, that any such transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.

In early 2019, we initiated a review of external assets that could be added to our pipeline of product candidates. In July 2019, in connection with this process, we entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which we acquired exclusive worldwide rights to develop and commercialize DSTAT for any and all uses. In January 2021, we acquired Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, including ONC201. In connection with these transactions, we are responsible for, and bear the future costs of, development and commercialization of the acquired compounds. These costs will be substantial, and we may require additional capital in order to pursue the development and commercialization of these compounds as planned. Moreover, the anticipated benefits of these transactions may never be realized due to the various risks and uncertainties associated with drug development detailed elsewhere in the risk factors.

In addition to our current assets, we may in-license or acquire additional assets, engage in a merger or acquisition transaction, issue additional shares of our common stock, or engage in other potential actions designed to maximize stockholder value. Our continuing review of external assets may not result in the identification or consummation of any transaction. The process of reviewing external opportunities may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying, evaluating, negotiating, and consummating potential transactions. There can be no assurance that any potential additional transaction, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. In addition, once any potential additional transaction is consummated, we are likely to incur substantial costs associated with future development and testing of any new product candidate, which may require us to raise additional capital.

Risks Related to Clinical Development and Regulatory Approval

We face risks related to the coronavirus (COVID-19) outbreak, which could significantly disrupt our preclinical studies and clinical trials.

The duration and the geographic impact of the business disruption and related financial impact resulting from the coronavirus cannot be reasonably estimated at this time and our business could be adversely impacted by the effects. We are currently conducting clinical trials of our product candidates in the United States. We rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our non-clinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs. Similarly, clinical site initiation and patient enrollment may be delayed due to concerns for patient safety and prioritization of healthcare resources toward the COVID-19 pandemic. We also rely on third party suppliers and contract manufacturers to produce the drug product we utilize in our clinical trials, and the outbreak may cause delays in delivery and increases in the cost of active pharmaceutical ingredients (APIs) and drug product. As a result, the expected timeline for data readouts of our non-clinical studies and clinical trials and certain regulatory filings may be negatively impacted, and our APIs and drug product may become more expensive to obtain. The COVID-19 pandemic is also causing disruption of global financial markets which, if sustained or recurrent, could make it more difficult for us to access capital. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change, and may adversely affect our business, healthcare systems and the global economy as a whole.

We have only received regulatory approval for TEMBEXA, and all our other product candidates are still under clinical development and may not obtain regulatory approval or be successfully commercialized.

We have not marketed, distributed or sold any products. Our product candidates are ONC201, which we are developing for the treatment of recurrent H3 K27M-mutant glioma, as well as DSTAT, which we are developing for the treatment of AML and other potential indications. We are in late-stage clinical development for both ONC201 and DSTAT.

There is no guarantee that our current or future clinical trials will be approved by regulators, and no guarantee that they will be completed or, if completed, will be successful, or if successful, will result in an approval for the sale of any of our product candidates. The success of each of DSTAT, ONC201 and TEMBEXA will depend on several factors, including the following:

- generating positive safety and efficacy data from our clinical trials of DSTAT and ONC201;
- receipt of marketing approvals from the FDA and corresponding regulatory authorities outside the United States;
- establishing manufacturing capabilities necessary for a registration trial and commercialization of DSTAT;
- establishing commercial manufacturing capabilities for TEMBEXA;
- acceptance of the product, if approved for marketing;
- effectively competing with other therapies;
- a continued acceptable safety profile of the product following approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize TEMBEXA, ONC201, and DSTAT, which would materially harm our business.

We may be unable to obtain, or may be delayed in obtaining, regulatory approval for our most advanced clinical candidates: ONC201 and DSTAT.

In July 2019, we entered into a license agreement with Cantex where we acquired an exclusive license to global development and commercialization rights to DSTAT. We are currently enrolling our 570-subject Phase 3 **D**ociparstat in **A**ML with **S**tandard C**h**emotherapy (DASH AML) study of DSTAT for the treatment of AML.

In January 2021, we acquired Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, a novel potential class of compounds. Oncoceutics' lead product candidate, ONC201, is currently being evaluated in multiple clinical studies including in a potentially registrational program for recurrent H3 K27M-mutant glioma.

We have not yet reached agreement with the FDA or foreign regulators regarding the adequacy of these planned studies, for any of our most advanced clinical candidates, with respect to a potential approval for marketing. We may be required to conduct additional clinical, nonclinical or manufacturing validation studies and submit those data before reconsideration of our application occurs. Depending on the extent of these or any other required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA and/or foreign health authorities to approve our NDA or foreign application.

In particular, based on discussions with the FDA, we plan to integrate data from ongoing ONC201 trials into a registration cohort with the potential for an NDA submission seeking accelerated approval of ONC201 in the United States. Recently, the FDA has announced that the agency's Oncology Center of Excellence reassessed the marketing authorizations for several oncology medicines that received accelerated approvals where their confirmatory clinical trials did not demonstrate clinical benefit. It is possible that the occurrence or outcome of such reassessment may make it more difficult for us to apply for or obtain accelerated approval based on data from ongoing trials of our clinical candidates ONC201 and DSTAT. It is also possible that confirmatory clinical trials may not demonstrate clinical benefit.

Any delay in obtaining, or an inability to obtain, regulatory approvals could prevent us from generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for ONC201 and/or DSTAT, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We depend on the successful completion of clinical trials for our product candidates, including ONC201 and DSTAT. The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.

Before obtaining regulatory approval for the sale of our product candidates, including ONC201 and DSTAT, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult

to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

We may experience a number of unforeseen events during, or as a result of, clinical trials for our product candidates, that could adversely affect the completion of our clinical trials, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we might be required to change one of our clinical research organizations (CROs) during ongoing clinical programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks, or other factors such as the impact of the ongoing COVID-19 pandemic;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory or quality requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- we may encounter agency or judicial enforcement actions which impact our clinical trials;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our most advanced product candidates, including ONC201 and DSTAT. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for any of our product candidates may be adversely impacted.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in a delay or unsuccessful completion of clinical trials, including our currently planned or future clinical trials for either ONC201 or DSTAT, include:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining, or failure to obtain, regulatory approval of Investigational New Drug applications or to commence a trial;
- delays in reaching agreement with the FDA and foreign health authorities on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays caused by disagreements with existing CROs and/or clinical trial sites;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining, or failure to obtain, required IRB or ethics committee (EC) approvals covering each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;

- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- clinical sites declining to participate or dropping out of a trial to the detriment of enrollment;
- agency or judicial enforcement actions against us;
- changes in standard of care in specific diseases;
- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

Many of the above factors may be caused or exacerbated by the impact of the ongoing COVID-19 pandemic. If initiation or completion of any of our clinical trials for our product candidates, are delayed for any of the above reasons, our development costs may increase, our approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may have more time to bring products to market before we do. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events (AEs) caused by our product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. For example, subjects enrolled in clinical trials for DSTAT have experienced febrile neutropenia and liver enzyme elevations. If an unacceptable frequency and/or severity of AEs are reported in our clinical trials for our product candidates, our ability to obtain regulatory approval for product candidates may be negatively impacted.

If any of our approved products cause serious or unexpected side effects prior to or after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may approve the product only with a risk evaluation and mitigation strategy (REMS), potentially with restrictions on distribution and other elements to assure safe use (ETASU);
- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize any of our product candidates and we cannot, therefore, predict the timing of any future revenue from ONC201 or DSTAT.

We cannot commercialize our product candidates, including ONC201 and DSTAT, until the appropriate regulatory authorities have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for any of our product candidates. Delays may occur because we may not be able to obtain accelerated approval for our product candidates and large confirmatory studies may be needed. For ONC201, a comparison diagnostic test may be needed to identify patients with H3 K27M-mutant glioma before approval. Additional delays in the United States may result if any of our product candidates is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In the EU context, an Oral Explanation during MAA review could extend approval timelines and result in a Negative Opinion. A re-examination procedure is available in the EU whereby a Negative Opinion could be over-turned and become a Positive Opinion. New rapporteurs would be selected for the product. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates.

Failure by us or third-party collaborators to successfully develop, validate and obtain regulatory approval for companion diagnostics for use by oncologists could harm our ability to develop and commercialize ONC201.

For ONC201, a diagnostic test is used to identify patients with H3 K27M-mutant glioma. FDA may require approval of a comparison diagnostic in connection with an approval of ONC201 NDA. We intend to rely on third-parties for development of companion diagnostics for commercialization of ONC201. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices. Any failure by a third party to obtain FDA clearance or approval for an H3 K27M mutation diagnostic test would impair our ability to meet FDA commitments for ONC201.

The FDA may determine that ONC201 or any of our other product candidates, if approved, do not meet the eligibility criteria for a priority review voucher.

Upon regulatory approval of a product candidate for a designated rare pediatric disease, neglected tropical disease, or medical countermeasure, the FDA may award to the sponsor of the treatment a transferable voucher that enables the bearer to priority review of another product candidate.

The FDA has granted rare pediatric disease designation to ONC201 for treatment of H3 K27M-mutant glioma. Designation of a drug for a rare pediatric disease does not guarantee that an NDA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the Federal Food, Drug, and Cosmetic Act (FDCA), we will need to request a rare pediatric disease priority review voucher in our original NDA for ONC201. The FDA may determine that an NDA for ONC201, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- treatment of H3 K27M-mutant glioma no longer meets the definition of a rare pediatric disease;
- the NDA contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in an NDA;
- the NDA is not deemed eligible for priority review;
- the NDA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the NDA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the NDA is approved for a different adult indication than the rare pediatric disease for which ONC201 is designated.

The authority for the FDA to award rare pediatric disease priority review vouchers for drugs that have received rare pediatric disease designation prior to September 30, 2024 currently expires on September 30, 2026, although it is possible the FDA's authority to award rare pediatric disease priority review vouchers will be further extended through federal lawmaking. Absent any such extension, if the NDA for ONC201 is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher.

Similar risks apply to any of our other product candidates that may be eligible for a priority review voucher.

Following regulatory approval for TEMBEXA, or should any of our product candidates be approved, including ONC201 and DSTAT, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval, the granting authority may still impose significant restrictions on the indicated uses, distribution or marketing of TEMBEXA or our product candidates, including ONC201 and DSTAT, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for our product candidates, will likely include restrictions on use due to the specific patient population and manner of use in which the drug was evaluated and the safety and efficacy data obtained in those evaluations. In addition, the distribution of any of our product candidates may be tightly controlled through a REMS with ETASU, which are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient.

With respect to the FDA's approval of TEMBEXA for the treatment of smallpox, we received approval according to the Animal Rule and are subject to certain post-approval requirements. For example, we will need to conduct a large confirmatory clinical trial during a smallpox outbreak, which may be expensive and time-consuming and may not confirm the benefit making the marketing approval for TEMBEXA subject to withdrawal by the FDA, which could significantly harm our business. This study may be difficult to enroll due to the size and/or location of the smallpox outbreak. These outbreak studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in

further labeling restrictions that could impair or restrict the way in which we are able to market TEMBEXA, or negatively impact its overall clinical profile. We are currently in discussion with NIH regarding the development of a study protocol for which, NIH would serve as study sponsor. In addition, we will need to conduct in vitro resistance testing to address post-marketing commitments which could negatively impact the labeling.

Our product candidates will also be subject to additional ongoing regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. In the United States, the holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. If a REMS is required, the NDA holder may be required to monitor and evaluate those in the healthcare system who are responsible for implementing ETASU measures. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Moreover, EU and member countries impose strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the U.S., EU and in other territories. Physicians, on the other hand, may prescribe products for off-label uses in the U.S. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by regulatory authorities for compliance with Current Good Manufacturing Practices (cGMP), and adherence to commitments made in the application. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any product candidates, a regulatory agency may:

- issue an untitled or warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending application or supplements to an application submitted by us;
- recall and/or seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and inhibit our ability to generate revenues.

Having obtained FDA approval for TEMBEXA in the United States does not mean we will ever obtain approval for or commercialize TEMBEXA, ONC201,* DSTAT, *or any other products outside of the United States, nor does approval of any of our products outside the United States mean we will ever obtain approval for or commercialize any other products inside the United States, all of which could limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in any markets. If we fail to comply with regulatory requirements in

international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Conversely, approval by regulatory authorities outside the United States, such as the European Commission, does not ensure approval by the FDA. Moreover, clinical trials conducted outside the United States may not be accepted by the FDA.

Coverage and adequate reimbursement may not be available for ONC201, DSTAT or any of our other current or future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of ONC201, DSTAT, or any other product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and adequate reimbursement will be available from third-party payers, including government health administration authorities, managed care organizations and private health insurers. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Third-party payers in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure that other payers will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payer's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payers are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Even if favorable coverage and reimbursement status is attained for our products candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Our relationships with investigators, health care professionals, consultants, third-party payers, and customers may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and others play a primary role in the recommendation and prescribing of any products for which we obtain marketing approval. Our current business operations and future arrangements with investigators, healthcare professionals, consultants, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal healthcare anti-kickback statute which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the Federal Civil False Claims Act (False Claims Act) which permit private individuals to bring a civil action on behalf of the federal government to enforce certain of these laws thought civil whistleblower or *qui tam* actions and the Federal Civil Monetary Penalties Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, and their business associates as well as their covered subcontractors;

- the General Data Protection Regulation (GDPR), which impose obligations on companies in relation to the handling of personal data of individuals within the EU, along with related national legislation;
- mandated physician payments reporting laws and/or requirements throughout global jurisdictions, including EU member states, in which we conduct research and development and/or other business activities;
- the FDCA which prohibits, among other things, the adulteration or misbranding of drugs and devices;
- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies to report to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payers, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations 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 these or any other health regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and/or divert our management's attention from the operation of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they also may be subject to significant criminal, civil or administrative sanctions, including, but not limited to, exclusions from government funded healthcare programs, which could also materially affect our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. However, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018 (the BBA), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increased in the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. Additionally, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and other litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

Additionally, 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, presidential executive orders, 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. The FDA also released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services (DHHS) finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation (MFN) executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model on December 27, 2021, CMS published a final rule that rescinded the MFN model interim final rule. In July 2021, the Biden administration released an executive order with multiple provisions aimed at prescription drugs. In response to this executive order, in September 2021, DHHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions DHHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Such reform efforts are likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price that we receive for any future approved product. It is possible that additional governmental action may be taken in response to the COVID-19 pandemic. We cannot predict what healthcare reform initiatives may be adopted in the future.

Risks Related to Our Reliance on Third Parties

We rely on third-party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidates, including TEMBEXA.

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing with respect to TEMBEXA or our other product candidates, including ONC201 and DSTAT. In the past, we have relied on third-party manufacturers for supply of our preclinical and clinical drug supplies. We expect that in the future we will continue to rely on such manufacturers for drug supply that will be used in clinical trials and for commercialization of any of our product candidates that receive regulatory approval.

In July 2019, we were assigned Cantex's rights under a supply agreement with Scientific Protein Laboratories LLC (SPL) pursuant to which SPL will exclusively produce DSTAT for us through October 2040. We have agreed that SPL will be our exclusive provider of DSTAT bulk drug substance during the term of the agreement.

Our reliance on third-party manufacturers entails risks, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, or other factors such as the impact of the ongoing COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA or equivalent foreign regulator action, including injunction, recall, seizure, or total or partial suspension of production. The severity of the coronavirus (COVID-19) pandemic could make access to our existing supply chain difficult or impossible and could materially impact our business.

We rely on limited sources of supply for the drug components for TEMBEXA as well as each of our product candidates including ONC201 and DSTAT, and any disruption in the chain of supply for any of these product candidates may cause delays in their development and commercialization.

Manufacturing of drug components is subject to certain FDA and comparable foreign qualifications with respect to manufacturing standards. Our manufacturing of TEMBEXA is comprised of separate processes for each of bulk drug substance, tablets, and suspension. In addition, each of these forms can be manufactured at either small or large scale. For each form and scale of manufacturing, the process must be validated in order to supply TEMBEXA commercially. We have validated the TEMBEXA drug substance manufacturing process at our selected contractor that will produce drug substance at large scale. We have selected our TEMBEXA tablet and suspension manufacturers that will produce at both small and large scale. We have scaled up the tablet manufacturing process and plan to scale up the suspension manufacturing process to meet forecasted demand. There can be no assurance that manufacturing the suspension at large scale will be successful or will be completed in a timely fashion in order to meet large scale demands. If we are unable to successfully scale up to meet forecasted demands our business could be materially harmed.

In connection with the approval of TEMBEXA, we have only one supplier of drug substance and one separate supplier of drug product qualified as vendors with the FDA. We plan to validate the DSTAT and ONC201 drug substance and drug product processes prior to regulatory approval. It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified as vendors with the FDA for each of DSTAT and ONC201. If supply from an approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new drug substance or drug product supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of DSTAT, ONC201 or TEMBEXA, and cause us to incur additional costs. As an example, we source a significant number of materials used in the manufacture of our products from China; the impact of the recent coronavirus outbreak could make access to our existing supply chain difficult or impossible and could materially harm our business. If our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials for DSTAT, ONC201 and TEMBEXA may be delayed, which could inhibit our ability to generate revenues.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization of TEMBEXA, ONC201 and DSTAT.

We have validated processes for drug substance and drug product production for TEMBEXA.

We plan to validate DSTAT and ONC201 drug substance and drug product processes prior to approval at our selected vendors. It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified as vendors for each of DSTAT and ONC201 with the FDA.

As more batch data is generated post-validation for both the drug substance and drug products, and as additional stability data is collected, issues may arise in our processes and stability programs which could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of our products and product candidates. In the future, we may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical program and regulatory approval for our products and product candidates, increases in our operating expenses, or failure to obtain or maintain approval for each of DSTAT, ONC201 or in the case of TEMBEXA, maintain approval.

We depend on SymBio for developing and commercializing TEMBEXA for human diseases other than orthopoxviruses, including smallpox.

In 2019, we entered into a licensing arrangement with SymBio, whereby SymBio is responsible for the future development and commercialization of TEMBEXA for human diseases other than orthopoxviruses, including smallpox. Under this arrangement, SymBio is responsible for conducting preclinical studies and clinical trials, obtaining required regulatory approvals for TEMBEXA in non-orthopox indications (e.g. smallpox), and manufacturing and commercializing TEMBEXA in those indications. Our right to receive milestone payments under the licensing agreement depends on the achievement of certain development, regulatory and commercial milestones by SymBio and our ability to receive royalties under the agreement depends on SymBio's successful commercialization of TEMBEXA in the licensed indications.

The development and commercialization of the non-orthopox uses of TEMBEXA in humans and our ability to receive potential milestones and royalty payments under the license agreement with SymBio, would be adversely affected if SymBio:

- lacks or does not devote sufficient time and resource to the development and commercialization of TEMBEXA;
- lacks or does not devote sufficient capital to fund the development and commercialization of TEMBEXA;
- develops, either alone or with others, products that compete with TEMBEXA;
- fails to gain the requisite regulatory approvals for TEMBEXA;
- does not successfully commercialize TEMBEXA;
- does not conduct its activities in a timely manner;
- terminates its license with us;
- does not effectively pursue and enforce intellectual property rights relating to TEMBEXA; or
- merges with a third-party that wants to terminate the collaboration.

We have limited or no control over the occurrence of any of the foregoing. Furthermore, disagreements with SymBio could lead to litigation or arbitration, which could be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization milestones and royalties based on further development and sales of TEMBEXA.

We rely on third parties to conduct, supervise and monitor our clinical studies and related data, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical programs for our product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's guidance for clinical trials conducted within the jurisdiction of the United States (or the foreign regulatory authority equivalent for clinical trials conducted outside the jurisdiction of the United States), which follows the International Council for Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply

with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize ONC201, DSTAT, TEMBEXA or any other product candidates. Disagreements with our CROs over contractual issues, including performance, compliance or compensation could lead to termination of CRO agreements and/or delays in our clinical program and risks to the accuracy and usability of clinical data. As a result, our financial results and the commercial prospects for our product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of TEMBEXA, ONC201, DSTAT and any other product candidates will depend upon the acceptance of these products by the medical community, including physicians, patients, pharmacists, health care payers or government procurement agencies (e.g. BARDA).

Following receipt of marketing approval, a product or product candidate may not gain sufficient market acceptance by physicians, patients, healthcare payers and others in the medical community. If these products do not achieve an adequate level of market acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy in our clinical trials;
- relative convenience, ease of administration and acceptance by physicians, patients, pharmacists and health care payers;
- prevalence and severity of any AEs;
- limitations or warnings contained in the FDA-approved labeling from Regulatory Authorities such as the FDA and EMA for the relevant product candidate;
- availability, efficacy and safety of alternative treatments;
- price and cost-effectiveness;
- effectiveness of our or any future collaborators' or competitor's sales and marketing strategies;
- ability to obtain hospital formulary approval;
- ability to ensure availability for product through appropriate channels;
- ability to maintain adequate inventory; and
- ability to obtain and maintain sufficient third-party coverage and adequate reimbursement, which may vary from country to country.

Even if we obtain regulatory approval, the granting authority may still impose significant restrictions on the indicated uses, distribution or marketing of TEMBEXA or our other product candidates, including ONC201 and DSTAT, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for our product candidates, will likely include restrictions on use due to the specific patient population and manner of use in which the drug was evaluated and the safety and efficacy data obtained in those evaluations. In addition, the distribution of ONC201 or DSTAT may be tightly controlled through a REMS with ETASU, which are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient. Some actions may also be required in order for the patient to continue on treatment. For example, the label for TEMBEXA includes a boxed warning, or "black box," regarding the mortality disadvantage with extended dosing observed in the SUPPRESS trial.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We currently do not have an organization for the sales and distribution of pharmaceutical products. The cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be

approved we must establish our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our product candidates.

Our strategy for each of ONC201 and DSTAT, is to establish a specialty sales force and/or collaborate with third parties to promote the product to healthcare professionals and third-party payers in the United States and elsewhere. We may elect to launch with a contract sales organization and utilize accompanying commercial support services provided by a contract sales organization. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the distribution and sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that are not covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales, including sales of ONC201 and DSTAT, will be adversely affected.

Establishing an internal or contract sales force involves many challenges, including:

- recruiting and retaining talented people;
- training employees that we recruit;
- establishing compliance standards;
- setting the appropriate system of incentives;
- managing additional headcount;
- ensuring that appropriate support functions are in place to support sales force organizational needs; and
- integrating a new business unit into an existing corporate architecture.

If we are unable to establish our own sales force or negotiate a strategic partnership for the commercialization of our product candidates in any markets, we may be forced to delay the potential commercialization of our product candidates in those markets, reduce the scope of our sales or marketing activities for our product candidates in those markets or undertake the commercialization activities for in those markets at our own expense. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market or generate product revenue. Limited or lack of funding will impede our ability to achieve successful commercialization.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing and market access personnel.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our product candidates are approved for commercialization, we may enter into agreements with third parties to market those product candidates outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in the EU and other foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory and labor requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

- differing payer reimbursement regimes, governmental payers or patient self-pay systems and price controls;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- regulatory risks associated with cross-border transportation of animal-sourced material;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters and other events outside our control including epidemics, pandemics, earthquakes, typhoons, floods and fires; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions, or similar anti-bribery or anti-corruption laws and regulations.

We have limited experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the individual countries in Europe with which we will need to comply. Many U.S.-based biopharmaceutical companies have found the process of marketing their own products outside the United States to be very challenging.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our competitors have substantially greater financial, technical, commercial and other resources, such as larger research and development staff, stronger intellectual property portfolios and experienced marketing and manufacturing organizations and established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug products that are more effective or less costly than TEMBEXA, or any of our drug candidates that we are currently developing or that we may develop including ONC201 and DSTAT.

We will face competition from other drugs currently approved or that will be approved in the future for the same indications. Therefore, our ability to compete successfully will depend largely on our ability to:

- discover and develop medicines that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates, including ONC201 and DSTAT, are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain and successfully defend and enforce patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines;
- deliver a competitive value proposition compared to established competition and/or competitors who will enter the market before or after any of our product candidates, including TEMBEXA, ONC201 and DSTAT; and
- negotiate competitive pricing and reimbursement with third-party payers.

The availability of our competitors' products could affect the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates. Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our research methodology or that of our collaboration partners may be unsuccessful in identifying potential product candidates;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- our collaboration partners may change their development profiles for potential product candidates or abandon a therapeutic area.

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

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other countries. If this were to occur, early generic competition could be expected against any product candidates we may develop. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability, scope or ownership, which may result in such patents, or our rights to such patents, being narrowed or invalidated.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold or license with respect to any of our product candidates fails to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable, will go unthreatened by third parties or will adequately protect our products and product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market DSTAT and TEMBEXA under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to any of our product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be possible. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we

cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Further, the laws of some foreign countries do not protect patents and other proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property abroad. We may also fail to pursue or obtain patents and other intellectual property protection relating to our products and product candidates in all foreign countries.

Finally, certain of our activities and our licensors' activities have been funded, and may in the future be funded, by the U.S. federal government. When new technologies are developed with U.S. federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of ONC201, DSTAT, TEMBEXA and/or any other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. 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. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay

royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors and licensees or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counterclaims against us.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in a litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. 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. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, we may lose our rights and our competitors might be able to enter the market, which would have a material adverse effect on our business.

Risks Related to Our United States Government Contracts and Grants

While we have received a sole source request from BARDA, there can be no assurances that we will be able to enter into a contract with BARDA on favorable terms, or at all, to act as the sole supplier for the procurement of TEMBEXA for the treatment of smallpox.

On December 22, 2021, BARDA issued a Request for Proposal (the “RFP”) to the Company, which confirmed, among other things, BARDA’s intent to negotiate a sole source contract with the Company for the development and procurement of a smallpox therapeutic with a mechanism of action distinct from that of TPOXX® (marketed by SIGA Technologies, Inc. (“SIGA”)) and with a New Drug Application accepted by the U.S. Food and Drug Administration (the “FDA”). The issuance of

the RFP by BARDA is a requisite step in the sole source contracting process and allows the Company to commence negotiations with BARDA and to submit a proposal for a contract with BARDA.

The RFP indicates that BARDA intends to contract with the Company to procure up to 1.7 million treatment courses of a smallpox antiviral. The RFP also requires the Company to perform certain activities to be supported by BARDA, including, but not limited to the execution of a randomized clinical trial in the event of an outbreak, and certain cGMP manufacturing activities. The final terms of any contract awarded under the RFP will be subject to future negotiations between BARDA and the Company, including, but not limited to, provisions concerning costs, fees, manufacturing schedules, timing of deliverables, duration and termination. The RFP requests any responsive proposals be submitted to BARDA no later than February 7, 2022 at 12 PM ET. The Company submitted a proposal for a sole source contract to BARDA prior to the submission deadline.

Furthermore, while our proposal remains under review with BARDA regarding the RFP, there can be no assurance that we would reach agreement with BARDA on favorable terms, or at all, related to the manufacture and delivery of TEMBEXA to the SNS. Among the material terms to be negotiated and agreed to are: price, volume, and payment and delivery schedules.

Unfavorable provisions in government contracts, including our contract with BARDA, may harm our business, financial condition and operating results.

United States government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our contract with BARDA, the U.S. government has the power to unilaterally:

- audit and object to any BARDA contract-related costs and fees on grounds that they are not allowable under the FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or extending our existing contract based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA contract and may, under certain circumstances, such as circumstances involving public health and safety, license such inventions to third parties without our consent;
- cancel, terminate or suspend our BARDA contract based on violations or suspected violations of laws or regulations;
- terminate our BARDA contract in whole or in part for the convenience of the government for any reason or no reason, including if funds become unavailable to the applicable governmental agency;
- reduce the scope and value of our BARDA contract;
- decline to exercise an option to continue the BARDA contract;
- direct the course of a development program in a manner not chosen by the government contractor;
- require us to perform the option segments even if doing so may cause us to forego or delay the pursuit of other opportunities with greater commercial potential;
- take actions that result in a longer development timeline than expected; and
- change certain terms and conditions in our BARDA contract.

The U.S. government also has the right to terminate the BARDA contract if termination is in the government’s interest, or if we default by failing to perform in accordance with the milestones set forth in the contract. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed (plus a portion of the agreed fee) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit recovery of fees.

In addition, we must comply with numerous laws and regulations that affect how we conduct business with the United States government. Among the most significant government contracting regulations that affect our business are:

- FAR, and agency-specific regulations supplements to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts and implement federal procurement policy in numerous areas, such as employment practices, protection of the environment, accuracy and retention periods of records, recording and charging of costs, treatment of laboratory animals and human subject research;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Furthermore, we may be required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors, in order to satisfy our contractual obligations pursuant to our agreements with the U.S. government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our government contract. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our contract.

As a result of these unfavorable provisions, we must undertake significant compliance activities. The diversion of resources from commercial programs to these compliance activities, as well as the exercise by the U.S. government of any rights under these provisions, could materially harm our business.

Our business is subject to audit by the U.S. government, including under our contract with BARDA, and a negative audit could adversely affect our business.

United States government agencies, such as the DHHS, routinely audit and investigate government contractors and recipients of federal grants, including our contract with BARDA. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DHHS can also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us by the U.S. government, which could adversely affect our business.

Agreements with government agencies may lead to claims against us under the Federal False Claims Act, and these claims could result in substantial fines and other penalties.

The biopharmaceutical industry is, and in recent years has been, under heightened scrutiny as the subject of government investigations and enforcement actions. Our BARDA contract is subject to substantial financial penalties under the Federal Civil Monetary Penalties Act and the False Claims Act. The False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false record or statement material to a false or fraudulent claim paid or approved by the government. Under the False Claims Act's "whistleblower" provisions, private enforcement of fraud claims against businesses on behalf of the U.S. government has increased due in part to amendments to the False Claims Act that encourage private individuals to sue on behalf of the government. These whistleblower suits, known as *qui tam* actions, may be filed by private individuals, including present and former employees. The False Claims Act provides for treble damages and significant civil monetary penalties per false claim. If our operations are found to be in violation of any of these laws, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

Risks Related to Our Business Operations and Industry

Increasing demand for compassionate use of our unapproved therapies could result in losses.

Recent media attention to individual patients' expanded access requests has resulted in the introduction of legislation at the local and national level referred to as "Right to Try" laws, such as the Right to Try Act, which are intended to give patients access to unapproved therapies. New and emerging legislation regarding expanded access to unapproved drugs for life-threatening illnesses could negatively impact our business in the future. In addition, during 2014, we were the target of an active

and disruptive social media campaign related to a request for access to TEMBEXA. If we experience similar social media campaigns in the future, we may experience significant disruption to our business which could result in losses.

A possible consequence of both activism and legislation in this area is the need for us to initiate an unanticipated expanded access program or to make ONC201, DSTAT or TEMBEXA more widely available sooner than anticipated. We are a small company with limited resources and unanticipated trials or access programs could result in diversion of resources from our primary goals.

In addition, patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and have exhausted all other available therapies. The risk for serious adverse events in this patient population is high which could have a negative impact on the safety profile of our product candidates, which could cause significant delays or an inability to successfully commercialize them, which could materially harm our business. We may also need to restructure or pause ongoing compassionate use and/or expanded access programs in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of our product candidates, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, delays in the development of our product candidates, penalties and a loss of business.

Our activities, and the activities of our collaborators, partners and third-party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of healthcare companies. In addition, pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulations, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, submission of false claims for government reimbursement, antitrust violations, violations of the Foreign Corrupt Practices Act, or violations related to environmental matters. Violations of governmental regulation may be punishable by criminal, civil and administrative sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid. In addition to penalties for violation of laws and regulations, we could be required to delay or terminate the development of our product candidates, or we could be required to repay amounts we received from government payers, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. To help attract, retain, and motivate qualified employees, we use share-based incentive awards such as employee stock options and restricted stock units. If our share-based compensation ceases to be viewed as a valuable benefit, our ability to attract, retain, and motivate employees could be weakened, which could harm our results of operations.

We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of appropriately skilled executives in our industry, which is likely to continue. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, failure of any of our clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee may adversely affect the progress of our research, development and commercialization objectives.

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 be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us, which could also adversely affect the progress of our research, development and commercialization objectives.

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

The use of our product candidates, including ONC201 and DSTAT, in clinical studies and the sale of any products for which we obtain marketing approval, including TEMBEXA, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical studies;
- significant costs to defend the related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize TEMBEXA or our product candidates, including ONC201 and DSTAT; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently carry $15 million in product liability insurance covering our clinical trials, but not yet extending coverage to commercial sales. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to initiate or continue our planned, ongoing and future clinical trials, disrupt regulatory activities, disrupt our ability to maintain a commercial infrastructure for our products or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019, has spread worldwide, causing many governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restrictions, heightened border scrutiny, and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the pandemic and its effects on our business and operations are uncertain.

In the event of a continuation of shelter-in-place orders and/or other mandated local travel restrictions, our employees conducting research and development activities may not be able to access our research space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time. In light of the pandemic, we may choose to pause certain research programs, delay the start of certain longer-term clinical studies and limit hiring.

We may face difficulties recruiting or retaining patients in our ongoing clinical trials because of the pandemic. For example, patients for our recently initiated trial of DSTAT as a treatment for AML may be unable or unwilling to visit clinical trial sites which may impact the collection of important clinical trial data or such a delay may alter DSTAT's potential time to market which could reduce its commercial attractiveness in a competitive AML marketplace. In addition, limitations in the ability to visit sites may adversely affect, our enrollment timelines for our clinical trials, and may adversely affect the timing of completion of our clinical trials or our ability to complete clinical trials in a fully compliant manner. Additionally, the potential suspension of clinical trial activity at clinical trial sites may have an adverse impact on our clinical trial plans and timelines.

We may face disruptions that may affect our ability to initiate and complete clinical trials including disruptions in procuring items that are essential for our research and development activities, including, for example, raw materials used in the manufacturing of our product candidates and laboratory supplies for planned and ongoing clinical trials, in each case, for which there may be shortages because of ongoing efforts to address the outbreak. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring, data collection, data integrity and data analysis may be paused or delayed or negatively impacted due to changes in hospital or university policies, federal, state or

local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. We may face manufacturing disruptions or disruptions related to the ability to obtain necessary institutional review board (IRB) or other necessary site approvals, as well as other delays at clinical trial sites.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions.

The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

We may experience difficulties in integrating the operations of Oncoceutics into our business and in realizing the expected benefits of the merger with Oncoceutics.

The success of our merger with Oncoceutics (the Merger) will depend in part on our ability to realize the anticipated benefits from combining the operations of Oncoceutics with our business in an efficient and effective manner. The integration process could take longer than anticipated and could result in the loss of key employees, the disruption of each company's ongoing businesses, tax costs or inefficiencies, or inconsistencies in standards, controls, information technology systems, procedures and policies, any of which could adversely affect our ability to achieve the anticipated benefits of the Merger, and could harm our financial performance and impair stockholder value. If we are unable to successfully or timely integrate the operations of Oncoceutics with our business, we may incur unanticipated liabilities and be unable to realize the revenue growth, synergies and other anticipated benefits resulting from the Merger, and our business, results of operations and financial condition could be materially and adversely affected. We have incurred significant costs in connection with the Merger. The substantial majority of these costs are non-recurring expenses related to the Merger. We may incur additional costs in the integration of Oncoceutics, and may not achieve cost synergies and other benefits sufficient to offset the incremental costs of the Merger.

Risks Related To Our Common Stock

The market price of our common stock is likely to be volatile, and you may not be able to resell your shares at or above your purchase price.

The trading price of our common stock has been volatile, and is likely to continue to be volatile for the foreseeable future. Our stock price is subject to wide fluctuations in response to a variety of factors, including the following:

- results of clinical trials of our product candidates or those of our competitors;
- any delay in filing an application for any of our product candidates and any adverse development or perceived adverse development with respect to regulatory review of that application;
- failure to successfully develop and commercialize TEMBEXA or our product candidates, including ONC201 and DSTAT;
- termination of any of our license or collaboration agreements;
- any agency or judicial enforcement actions against us;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to our product candidates;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- significant lawsuits (including patent or stockholder litigation), and disputes or other developments relating to proprietary rights (including patents, litigation matters and our ability to obtain patent protection for our technologies);
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- general economic, industry and market conditions, including the impact of the ongoing COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

In addition, the stock market in general, and The Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

Based upon shares of common stock outstanding as of December 31, 2021, our then executive officers, directors, 5% stockholders (known to us through available information) and their affiliates beneficially owned approximately 31.5% of our voting stock. Therefore, these stockholders have the ability to substantially influence us through this ownership position. For example, these stockholders, if they choose to act together, may be able to influence the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting expense and expend significant management efforts. In this or future years, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the Securities and Exchange Commission, The Nasdaq Stock Market or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

In July 2019, we entered into a license agreement with Cantex where we acquired an exclusive license to global development and commercialization rights to DSTAT. As partial consideration for our rights under the license agreement, we issued to Cantex 10,000,000 shares of our common stock. We are continuing to review additional potential transactions to add to our pipeline of product candidates, and these transactions could involve the issuance of additional shares of common stock or other

equity securities. On January 7, 2021, we acquired Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, including ONC201. As part of the consideration for the acquisition, we paid an upfront cash payment of approximately $25.0 million and issued an aggregate of 8,723,769 shares of our common stock.

Pursuant to our 2013 Equity Incentive Plan (the 2013 Plan), our management is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2013 Plan will automatically increase on January 1st each year, through January 1, 2023, by an amount equal to 4.0% of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. In addition, our board of directors may grant or provide for the grant of rights to purchase shares of our common stock pursuant to the terms of our 2013 Employee Stock Purchase Plan (ESPP). The number of shares of our common stock reserved for issuance under our ESPP will automatically increase on January 1st each year, through January 1, 2023, by an amount equal to the lesser of 422,535 shares or one percent of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. Unless our board of directors elects not to increase the number of shares underlying our 2013 Plan and ESPP each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We have broad discretion in the use of the net proceeds from our financing transactions and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our financing transactions. Because of the number and variability of factors that will determine our use of the net proceeds from our financing transactions, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we have invested the net proceeds from our financing transactions in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Volatility in our stock price could subject us to securities class action litigation.

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

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. The Coronavirus Aid, Relief and Economic Security Act (CARES Act) has already modified certain provisions of the Tax Act, and the Biden administration and Congress have proposed various changes, which if enacted could have a material impact on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

Our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the Tax Act, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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

Our U.S. net operating loss (NOL) carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017, may be carried forward indefinitely. The CARES Act revised the NOL limitations such that the deductibility of federal NOLs generated in tax years beginning after December 31, 2020, is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change U.S. tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have determined that a Section 382 ownership change occurred in 2007 resulting in limitations of at least $762,000, of losses incurred prior to the ownership change date. In addition, we have determined that another Section 382 ownership change occurred in 2013 with our IPO, our most recent private placement and other transactions that have occurred since 2007, resulting in a limitation of at least $6.7 million of losses incurred prior to the ownership change date. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, our pre-2018 NOL carryforwards may expire prior to being used, and our NOL carryforwards generated in 2018 and thereafter will be subject to a percentage limitation. In addition, it is possible that we have in the past undergone, and in the future may undergo, additional ownership changes that could limit our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes.

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

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

Provisions in our corporate charter documents and under Delaware law could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Some provisions of our charter documents 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. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- allowing the authorized number of our directors to be changed only by resolution of our board of directors;
- limiting the removal of directors;
- creating a staggered board of directors;
- requiring that stockholder actions must be effected at a duly called stockholder meeting and prohibiting stockholder actions by written consent;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at duly called stockholder meetings.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require the affirmative vote of the holders of at least 66 2/3 percent of the voting power of all of our then outstanding common stock.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which

generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Risks Related to Information Technology

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology (IT) systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our IT systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of our ability to operate our business effectively.

In addition, our systems are potentially vulnerable to data security breaches-whether by employees or others-which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, business partners and others.

Any such disruption or security breach could result in legal proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disruptions to our operations and collaborations, and damage to our reputation, which could harm our business and results of operations.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable laws and regulations. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 2505 Meridian Parkway, Suite 100, Durham, North Carolina 27713 in a facility we lease encompassing approximately 21,325 square feet of office space. The leases for this facility expire in July 2026. We separately lease laboratory space in Durham, North Carolina, encompassing a total of approximately 7,925 square feet. The lease for this laboratory space in Durham expires in July 2026. Through our subsidiary, Oncoceutics, Inc., we lease month to month approximately 375 square feet of office space in Philadelphia, Pennsylvania.

We believe that our property and equipment are generally well maintained and in good operating condition.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Stock Performance Graph[(1)]

The following graph shows a comparison from December 31, 2015 through December 31, 2021 of the cumulative total return for our common stock, the Nasdaq Biotechnology Index (NBI) and the Nasdaq Composite Index (CCMP). The graph assumes an initial investment of $100 on December 31, 2015. The comparisons in the graph below are based upon historical data and are not intended to forecast or be indicative of possible future performance of our common stock or Indexes.

Comparison of Cumulative Total Return*
Among Chimerix, Inc., the Nasdaq Biotechnology Index and the Nasdaq Composite Index

[(1)] This section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.
* Assuming the investment of $100 on 12/31/2015 (and the reinvestment of dividends thereafter) in each of (i) Chimerix, Inc.'s common stock, (ii) the Nasdaq Biotechnology Index and (iii) the Nasdaq Composite Index.

Stockholders

As of February 25, 2022, there were 82 stockholders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. Additionally, the terms of our loan and security agreement with Silicon Valley Bank may prohibit us from declaring or paying dividends.

Recent Sales of Unregistered Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our securities during the period covered by this Annual Report.

ITEM 6. RESERVED

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

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Forward-Looking Statements."

Overview

Chimerix is a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. In June 2021, the U.S. Food and Drug Administration (FDA) approved TEMBEXA (brincidofovir) for the treatment of smallpox as a medical countermeasure. Our two most advanced clinical-stage development programs are ONC201 and dociparstat sodium (DSTAT). ONC201 is in development for recurrent H3 K27M-mutant glioma. DSTAT is in Phase 3 development as a potential first-line therapy in combination with standard chemotherapy for the treatment of acute myeloid leukemia (AML).

Recent Developments

TEMBEXA (brincidofovir, BCV)

On June 4, 2021, the FDA granted TEMBEXA approval for the treatment of smallpox. TEMBEXA is available in tablets and oral suspension. It is approved for adult and pediatric patients, including neonates. TEMBEXA was developed as a medical countermeasure for the treatment of smallpox under an ongoing collaboration with Biomedical Advanced Research and Development Authority (BARDA). On July 19, 2021, the FDA confirmed that, following the recent approval, TEMBEXA is entitled to seven years' orphan exclusivity in the U.S. for the treatment of smallpox beginning with the June 4, 2021 marketing approval. In addition to orphan exclusivity, TEMBEXA patent coverage in the U.S. is expected to extend into 2034.

TEMBEXA potentially fills an important role as a treatment countermeasure to smallpox; it has a differentiated mechanism of action, a relatively high barrier to resistance and available evidence suggests it can be used in patients who have received the other FDA approved smallpox antiviral treatment. In September, an article was published in the peer review journal, Antiviral Research, providing a thorough assessment of TEMBEXA as a medical counter measure for smallpox.

On December 22, 2021, BARDA issued a RFP, which confirmed, among other things, BARDA's intent to negotiate a sole source contract with us for the development and procurement of TEMBEXA. The RFP indicates that BARDA intends to contract with us to procure up to 1.7 million treatment courses of a smallpox antiviral. Currently our proposal is under review with BARDA. In addition, as a governmental agency, BARDA's ability to enter into a contract is subject to continued funding for this purpose, which can change at any time.

As of December 31, 2021, we had completed initial TEMBEXA drug product manufacturing in order to execute first shipments to the Strategic National Stockpile in response to a potential procurement contract to support national preparedness in the United States.

Imipridones - ONC201, ONC206 and ONC212

Imipridones are a potential new class of selective cancer therapies. Clinical trials of ONC201 in glioma patients with the H3 K27M-mutation are underway at several locations in the U.S. The Company plans to meet with the FDA in the first half of 2022 to review the design for the ONC201 first-line randomized, placebo-controlled Phase 3 trial in combination with radiation therapy. The Company plans to initiate this study in patients who harbor the H3 K27M mutation in the second half of 2022. Under a potential accelerated approval for ONC201 in H3 K27M positive recurrent diffuse midline glioma the FDA may require this trial to be underway. In addition, the Company is conducting a retrospective natural history study, completing other supporting clinical pharmacology data, CMC supporting data and compiling the safety package which it plans to review with the FDA.

ONC201 - Results from 50 Patient Cohort of ONC201 in Recurrent H3 K27M-mutant Glioma

On November 4, 2021, we reported top-line results from the blinded independent central review (BICR) efficacy analysis. The efficacy analysis by BICR of the 50-patient cohort determined the overall response rate (ORR) to be 20.0% (95% Confidence Interval (CI): 10.0-33.7%) as determined by Response Assessment in Neuro-Oncology Criteria for High Grade Gliomas (RANO-HGG). The median duration of response (mDOR) was 11.2 months (95% CI: 3.8 - not reached) and the median time to response (mTTR) was 8.3 months.

The cohort for a potential registration of ONC201 was comprised of the first 50 patients enrolled across five ONC201 clinical studies that met certain criteria. These patients were two years of age or older, had measurable diffuse midline glioma, harbored the H3 K27M mutation and had evidence of progression following prior therapy with at least radiation completed at least 90 days prior to enrollment, among certain other criteria.

One serious adverse event identified by an investigator was possibly related to ONC201. Full safety data collection and analysis for this cohort is ongoing. Prior safety review of ONC201 identified the most commonly reported adverse events (AEs) as nausea/vomiting, fatigue and decreased lymphocyte counts.

This data along with other supportive clinical data from the ONC201 clinical studies, a natural history evaluation, other supporting clinical pharmacology data, chemistry, manufacturing and controls (CMC) support, safety data and possible requirement to have an ongoing Phase 3 trial will be compiled for review at meetings expected to be requested with the FDA in 2022.

In accordance with the terms of the merger agreement between Chimerix and Oncoceutics, Inc., the achievement of the 20% ORR via BICR resulted in a success milestone payment of $20 million to the former Oncoceutics, Inc. shareholders paid prior to year-end.

ONC206 and ONC212

Phase 1 clinical trials for ONC206, our second imipridone product candidate, and IND-enabling work for our third imipridone candidate, ONC212, remain ongoing.

Dociparstat (DSTAT) for First-Line Acute Myeloid Leukemia (AML)

During 2020, we conducted an end of Phase 2 meeting with the FDA related to our development of DSTAT in AML, which informed the design of the Phase 3 trial. We are currently enrolling in our 570-subject Phase 3 Dociparstat in AML with Standard Chemotherapy (DASH AML) study of DSTAT for the treatment of AML. The multicenter, randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of DSTAT in combination with standard intensive induction and consolidation chemotherapy for the treatment of newly-diagnosed AML patients. Chimerix expects to unblind data following enrollment of the first 80 evaluable patients in this study to assess complete response rates and minimal residual disease rates between the study arm and the control arm. Enrollment of this study has proceeded more slowly than expected due to ongoing hospital staffing shortages related to COVID-19 and the competitive nature of enrolling subjects in this patient population. As such, we do not expect to complete enrollment of the first 80 evaluable patients by year end. We are reviewing a number of options to accelerate the development of DSTAT.

CMX521

Chimerix announced acceptance of a Late Breaking Oral presentation of CMX521 at the International Conference of Antiviral Research (ICAR) for March 23rd. Promising preclinical efficacy data generated using CMX521 as a potential prophylactic and treatment of SARS-CoV-2 (COVID-19) infection was generated through a collaboration between Chimerix and the Rapidly

Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC). READDI itself is a global public-private partnership founded at UNC by the UNC Eshelman School of Pharmacy, UNC School of Medicine, Gilling School of Global Public Health, Eshelman Institute for Innovation and the Structural Genomics Consortium. Monotherapy prophylactic administration of aerosol CMX521 every eight hours starting eight hours prior to infection reduced average viral titers in lung on day four post-infection by 3.62 $\log_{10}$ (>99.9% reduction) and prevented weight loss/clinical progression versus placebo. The model used in this study was also used in the development of another antiviral therapy which has Emergency Use Authorization for SARS-CoV-2 in the United States. Antiviral efficacy was also demonstrated with monotherapy treatment when CMX521 was initiated post-infection. When administered within 16 hours post-infection, CMX521 significantly reduced SARS-CoV-2 in the lung (Kruskal-Wallis $p<0.0001$) and protected mice from clinical symptoms of disease including weight loss and adverse lung pathology ($p<0.0001$) at day 4 post-infection relative to placebo.

Silicon Valley Bank Loan and Security Agreement

On January 31, 2022, we entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank. The Loan Agreement provides for a four-year secured revolving loan facility (the Credit Facility) in an aggregate principal amount of up to $50.0 million. Proceeds from the Credit Facility may be used for working capital and general corporate purposes.

We entered into the Loan Agreement to increase our financial flexibility by, among other things, providing a non-dilutive source of capital that can be drawn on to support our future working capital needs in light of the previously disclosed potential entry into a sole source contract with BARDA. We view the Credit Facility as a resource that will supplement our financial position by providing an alternative source of capital that can be utilized on an as-needed basis, for example, in advance of an anticipated (or future) shipment of TEMBEXA treatment courses to BARDA into the U.S. Strategic National Stockpile over the term of the Credit Facility.

We may borrow, repay and re-borrow funds under the Credit Facility without a prepayment penalty until January 31, 2026 (the Maturity Date), at which time the Credit Facility expires, and all outstanding revolving loans under the Credit Facility, together with all accrued and unpaid interest, must be repaid. No exit fee exists upon expiration of the Credit Facility on the Maturity Date. Subject to the satisfaction of certain liquidity ratios, the full $50.0 million of the Credit Facility will be available for us to borrow on a non-formula basis. If we are unable to meet these liquidity ratios, then availability under the Credit Facility is determined based on a borrowing base equal to percentages of certain accounts receivable and certain purchase orders (which include prospective options for BARDA to procure TEMBEXA treatment courses) in accordance with a formula set forth in the Loan Agreement.

Borrowings under the Credit Facility accrue interest at a floating per annum rate of the greater of (i) 1.50% above the Prime Rate (as defined below) and (ii) 4.75%. Prime Rate is defined as the rate of interest per annum published in The Wall Street Journal or any successor publication thereto as the “prime rate”. If such rate of interest from The Wall Street Journal becomes unavailable, the “Prime Rate” shall mean the rate of interest per annum announced by Silicon Valley Bank as its prime rate in effect. In each case, in the event such prime rate is less than zero, such rate shall be deemed to be zero for purposes of the Loan Agreement. We must also pay an unused line fee equal to 0.25% per annum on the unused portion of the Credit Facility, payable quarterly in arrears. Upon the termination of the Loan Agreement for any reason prior to the Maturity Date, the Company will be required to pay to Silicon Valley Bank an early termination fee of $0.5 million. The Loan Agreement also requires us to pay Silicon Valley Bank a non-refundable commitment fee of $0.5 million, payable in four equal installments beginning on the date of the Loan Agreement and each anniversary of such date thereafter until January 31, 2025.

Our obligations under the Loan Agreement are secured by a first lien on substantially all our assets other than our intellectual property, with a negative pledge on the intellectual property of our leading programs.

Business Development Review

In addition to our transactions with Cantex Pharmaceuticals, Inc. (Cantex), SymBio Pharmaceuticals Limited (SymBio) and Oncoceutics, Inc. (Oncoceutics), management is continuing to conduct a review and assessment of potential transaction opportunities with the goal of building our product candidate pipeline, including, but not limited to, licensing, merger or acquisition transactions, issuing or transferring shares of common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that this review will result in the identification or consummation of any additional transaction.

Financial Overview

Revenues

To date, we have not generated any revenue from product sales. All of our revenue to date has been derived from government grants and a contract and the receipt of up-front proceeds under our collaboration and license agreements.

In February 2011, we entered into a contract with BARDA, a U.S. governmental agency that supports the advanced research and development, manufacturing, acquisition, and stockpiling of medical countermeasures. The contract originally consisted of an initial performance period, referred to as the base performance segment, which ended on May 31, 2013, plus up to four extension periods, referred to as option segments, which have all been exercised. The contract was a cost-plus fixed fee development contract. Under the contract we received $72.5 million in expense reimbursement and $4.6 million in fees. The fourth and final option segment ended on September 1, 2021 and the contract expired in accordance with its terms. Under the BARDA contract, we recognized revenue of $1.6 million, $5.3 million, and $7.6 million during the twelve months ended December 31, 2021, 2020, and 2019, respectively.

In September 2019, we entered into a license agreement with SymBio for worldwide rights to develop, manufacture and commercialize TEMBEXA in all human indications, excluding the use for treatment of orthopoxviruses, including smallpox. Under the contract, we received a $5.0 million upfront payment in October 2019 and could receive up to an additional $180.0 million in potential regulatory and commercial milestones. Since the license agreement was entered into in September 2019, we have recognized all of the $5.0 million of revenue related to the upfront payment. The revenue from regulatory and commercial milestones and royalties from net sales will be recognized upon occurrence of the triggering events.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and royalties from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, milestone and other payments, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of any product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors. We cannot determine with certainty the duration and completion costs of the current or future clinical studies of any product candidates. Our research and development expenses consist primarily of:

- fees paid to consultants and contract research organizations (CROs), including in connection with preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- salaries and related overhead expenses, which include stock option, restricted stock units and employee stock purchase program compensation and benefits, for personnel in research and development functions;
- payments to third-party manufacturers, which produce, test and package drug substance and drug product (including continued testing of process validation and stability) for unapproved product candidates;
- costs related to legal and compliance with regulatory requirements; and
- license fees for and milestone payments related to licensed products and technologies.

The table below summarizes our research and development expenses for the periods indicated (in thousands). Our direct research and development expenses consist primarily of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, preclinical development, and payments to third-party manufacturers of drug substance and drug product. We typically use our employee and infrastructure resources across multiple research and development programs.

	Years Ended December 31,		
	2021	2020	2019
Direct research and development expenses	$ 26,808	$ 19,125	$ 22,101
Research and development personnel costs - excluding stock-based compensation	17,709	11,543	12,705
Research and development personnel costs - stock-based compensation	6,611	2,969	4,089
Indirect research and development expenses	22,689	2,595	3,393
Total research and development expenses	$ 73,817	$ 36,232	$ 42,288

The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the development of any product candidates or the period, if any, in which material net cash inflows from any product candidates may commence. This is due to the numerous risks and uncertainties associated with our business, as detailed in Part II, Item IA, “Risk Factors” in this Quarterly Report on Form 10-Q and in our other filings with the SEC.

TEMBEXA (Brincidofovir, BCV)

We developed TEMBEXA for the treatment of smallpox. FDA marketing approval for TEMBEXA was received on June 4, 2021. Under our cost-plus-fixed fee BARDA contract, we incurred expenses in connection with the development of orthopoxvirus animal models, the demonstration of efficacy and pharmacokinetics of TEMBEXA in the animal models, the conduct of clinical studies for subjects with DNA viral infections, the manufacture and process validation of bulk drug substance and TEMBEXA 100 mg tablets and TEMBEXA 10 mg/mL oral suspension, and submission of the NDAs to the FDA. In addition, we have incurred additional supportive costs for the development of TEMBEXA for smallpox that we did not seek reimbursement for from BARDA. We have incurred costs related to the manufacturing of TEMBEXA for a possible procurement contract. These costs were expensed as incurred until the June approval. Following the June approval, costs related to the manufacturing of TEMBEXA are recorded and shown as inventories on the Consolidated Balance Sheets.

Imipridones program

In January 2021, we acquired Oncoceutics. In connection with the transaction, we recorded $82.9 million of acquired in-process research and development expenses for the three months ended March 31, 2021, which included $25.0 million for an upfront payment to Oncoceutics, $43.4 million related to the fair value of 8,723,769 shares common stock issued to Oncoceutics, a $14.0 million promissory note due on the one-year anniversary of the acquisition, and $0.3 million related to transaction costs consisting primarily of legal and professional fees. As we continue to develop and prepare Oncoceutics’ lead compound, ONC201, for a U.S. regulatory approval, we expect to incur significant research and development expense. We also plan to incur development expenses in connection with the continued development of other Oncoceutics' compounds, including ONC206 and ONC212.

Dociparstat sodium (DSTAT)

As we continue to focus on the development of DSTAT for treatment of AML patients, we expect research and development expense to increase with the ongoing and planned clinical trials. We are currently enrolling our Phase 3 DASH AML trial.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, marketing, investor relations, information technology, legal, human resources and administrative support functions, including share-based compensation expenses and benefits. Other significant general and administrative expenses include costs related to commercial readiness efforts, accounting and legal services, costs of various consultants, director and officer liability insurance, occupancy costs and information systems.

Interest Income and Other, Net

Interest income and other, net consists primarily of interest earned on our cash, cash equivalents and short-term and long-term investments.

Share-based Compensation

The Financial Accounting Standards Board (FASB) authoritative guidance requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. Total consolidated share-based compensation expense of $12.3 million, $5.6 million and $9.5 million was recognized in the years ended December 31, 2021, 2020 and 2019, respectively. The share-based compensation expense recognized included expense for stock options, RSUs and our employee stock purchase plan purchase rights.

We estimate the fair value of our share-based awards to employees and directors using the Black-Scholes pricing model. This estimate is affected by our stock price as well as assumptions including the expected volatility, expected term, risk-free interest rate, expected dividend yield, expected rate of forfeiture and the fair value of the underlying common stock on the date of grant.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. In addition, our reported financial condition and results of operations could vary if new accounting standards are enacted that are applicable to our business.

Our significant accounting policies are described in Note 1 to our audited consolidated financial statements for the year ended December 31, 2021 included in this Annual Report. We believe that our accounting policies relating to revenue recognition, research and development prepaids and accruals, acquired IPR&D, inventories, investments and share-based compensation are the most critical to understanding and evaluating our reported financial results. We have identified these policies as critical because they both are important to the presentation of our financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. For more information regarding these policies, you should refer to Note 1 to our audited consolidated financial statements included in this Annual Report.

Revenue Recognition

Our revenues generally consist of (i) contract and grant revenue - revenue generated under federal and private foundation grants and contracts, and (ii) collaboration and licensing revenue - revenue related to non-refundable upfront fees, royalties and milestone payments earned under license agreements. Revenue is recognized in accordance with the criteria outlined in Accounting Standards Codification (ASC) 606 issued by the Financial Accounting Standards Board (FASB). Following this accounting pronouncement, a five-step approach is applied for recognizing revenue, including (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the entity satisfies a performance obligation.

Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, we entered into a contract with BARDA for the advanced development of TEMBEXA as a medical countermeasure in the event of a smallpox release. Under the contract, we received $72.5 million in expense reimbursement and $4.6 million in fees over the performance of one base segment and four option segments. Exercise of each option segment was solely at the discretion of BARDA. The Company assessed the services in accordance with the authoritative guidance and concluded that there was a potential of five separate contracts (one base segment and four option segments) within this agreement, each of which had a single performance obligation. All option segments (one through four) were exercised, as well as the base segment. The transaction price for each segment, based on the transaction price as defined in each segment contract,

was allocated to the single performance obligation for each contract. The transaction price was recognized over time by measuring the progress toward complete satisfaction of the performance obligation. For reimbursable expenses, this occurred as qualifying research activities were conducted based on invoices from company vendors. For the fixed fee, the progress toward complete satisfaction was estimated based on the costs incurred to date relative to the total estimated costs per the terms of each contract. The Company typically invoiced BARDA monthly as costs were incurred. Any amounts received in advance of performance were recorded as deferred revenue until earned. The base segment and first option segment were completed prior to adoption of ASC 606. The second and third option segments were completed on August 20, 2020. The fourth option segment was completed on September 1, 2021 and the contract has expired in accordance with its terms.

Grant Revenue

Grant revenue under cost-plus-fixed-fee grants from the federal government and private foundations is recognized as allowable costs are incurred and fees are earned. As a result of its acquisition of Oncoceutics, Inc. (Oncoceutics), the Company became the beneficiary of two federal grant programs and two grant programs with private foundations, of which the federal grant programs ended in the third quarter of 2021. At December 31, 2021, the Company has a deferred revenue balance of $0.2 million related to these grants. Additionally, for the twelve months ended months ended December 31, 2021, the Company recognized $0.4 million of grant revenue related to these grants.

SymBio Pharmaceuticals

On September 30, 2019, we entered into a license agreement with SymBio Pharmaceuticals Limited (SymBio) under which we granted SymBio exclusive worldwide rights to develop, manufacture and commercialize BCV for all human indications, excluding the prevention and treatment of orthopoxviruses, including smallpox. We assessed the agreement in accordance with the authoritative guidance and concluded that the SymBio contract includes multiple performance obligations. The SymBio contract has one fixed transaction amount of a $5.0 million upfront payment received in October 2019 and several variable transaction amounts, up to $180 million, due to us at certain regulatory and commercial milestones, along with low double-digit percent royalties based on net sales of BCV. All variable transaction amounts are fully constrained, therefore the allocated transaction price is $5.0 million. The majority of the transaction price of the contract has been allocated to the combined performance obligation of the granting of the license to BCV and associated technology transfer which was recognized when the technology transfer was completed in the fourth quarter of 2019. The revenue from regulatory and commercial milestones and royalties from net sales will be recognized upon the occurrence of the triggering events or when those transaction amounts are no longer fully constrained.

Research and Development Prepaids and Accruals

As part of the process of preparing financial statements, we are required to estimate our expenses resulting from our obligation under contracts with vendors and consultants and clinical site agreements in connection with our research and development efforts. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts.

Our objective is to reflect the appropriate research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of our research and development efforts. We determine prepaid and accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of clinical trials, or other services completed. We adjust our rate of research and development expense recognition if actual results differ from our estimates. We make estimates of our prepaid and accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period. Through December 31, 2021, there had been no material adjustments to our prior period estimates of prepaid and accruals for research and development expenses. Our research and development prepaids and accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Acquired In-Process Research and Development (IPR&D) Expense

We have acquired and may continue to acquire the rights to develop and commercialize new drug candidates. In accordance with Accounting Standards Codification, or ASC, Subtopic 730-10-25, Accounting for Research and Development Costs, the up-front payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired IPR&D in transactions other than a business combination provided that the drug has not

achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Upon obtaining regulatory approval for marketing, any subsequent milestone payments may be capitalized and amortized over the life of the asset.

Inventories

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs. We begin capitalization of these inventory related costs once regulatory approval is obtained. We primarily use actual costs to determine our cost basis for inventories.

At December 31, 2021, our inventory is related to TEMBEXA, which is being manufactured for the treatment of smallpox and potential delivery to the Strategic National Stockpile (SNS) for the U.S. government and other government agencies. TEMBEXA was approved by the FDA on June 4, 2021, at which time we began to capitalize inventory costs associated with TEMBEXA. Prior to FDA approval of TEMBEXA, all costs related to the manufacturing of TEMBEXA were charged to research and development expense in the period incurred as there was no alternative future use.

We value our inventories at the lower of cost or estimated net realizable value. We determine the cost of its inventories, which includes amounts related to materials, manufacturing costs, shipping and handling costs on a first-in, first-out (FIFO) basis. Work-in-process includes all inventory costs prior to packaging and labelling, including raw material, active product ingredient, and drug product. Finished goods include packaged and labelled products. Our inventories at December 31, 2021 consisted of $2.8 million of work-in-process and no finished goods.

Our assessment of market value requires the use of estimates regarding the net realizable value of its inventory balances, including an assessment of excess or obsolete inventory. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires it to utilize judgment. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for its products, product expiration dates and current sales levels. Our assumptions of future demand for its products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. In addition, our inventory may experience expiration of its shelf-life stability. During the twelve months ended December 31, 2021, we did not record a reserve for inventory as we assume TEMBEXA will be sold to the US government under a procurement contract with Biomedical Advanced Research and Development Authority (BARDA) or could be sold to other governmental agencies. Should no procurement contract be secured in the future, we may reserve part or all of our inventory balance, which would be included in cost of sales.

Investments

Investments consist primarily of commercial paper, corporate bonds, and U.S. Treasury securities. We invest in high-credit quality investments in accordance with our investment policy which minimizes the probability of loss.

Available-for-sale debt securities are carried at fair value as determined by quoted market prices, with the unrealized gains and losses, net of tax, reported as a separate component of stockholders' deficit. Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis in interest income (expense) and other, net. Investments with original maturities beyond three months at the date of purchase and which mature on, or less than twelve months from, the balance sheet date are classified as short-term. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term. We periodically review available-for-sale debt securities for other-than-temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We evaluate, among other things, the duration and extent to which the fair value of a security is less than its cost; the financial condition of the issuer and any changes thereto; and our intent to sell, or whether we will more likely than not be required to sell, the security before recovery of our amortized cost basis. Any such declines in value judged to be other-than-temporary on available-for-sale securities are reported in other-than-temporary impairment of investment.

Valuation of Share-Based Compensation

We record the fair value of share-based awards issued as of the grant date as compensation expense. We recognize compensation expense over the requisite service period, which is equal to the vesting period.

Share-based compensation expense includes stock options, RSUs and employee stock purchase plan purchase rights and has been reported in our Consolidated Statements of Operations and Comprehensive Loss as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Income Statement Classification:			
Research and development expense	$ 6,611	$ 2,969	$ 4,089
General and administrative expense	5,649	2,599	5,439
Total stock-based compensation expense	$ 12,260	$ 5,568	$ 9,528

RSU compensation expense is based on the grant-date fair value of our common stock.

We calculate the fair value of share-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and the fair value of the underlying common stock on the date of grant. In applying these assumptions, we considered the following factors:

- We use historical volatility data to estimate the volatility of our common stock price.
- We use historical exercise data to estimate expected term.
- We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.
- The assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future.
- We estimate forfeitures based on our historical analysis of actual stock option forfeitures.

The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2021, 2020, and 2019 are set forth below:

Stock Options

	Years Ended December 31,		
	2021	2020	2019
Expected volatility	95.84 %	93.24 %	88.77 %
Expected term (in years)	6.0	6.0	6.0
Weighted-average risk-free interest rate	0.71 %	1.24 %	2.42 %
Expected dividend yield	— %	— %	— %
Weighted-average fair value per option	$ 6.67	$ 1.78	$ 1.71

Employee Stock Purchase Plan

	Years Ended December 31,		
	2021	2020	2019
Expected volatility	97.54 %	75.39 %	57.22 %
Expected term (in years)	0.71	1.28	1.23
Weighted-average risk-free interest rate	0.25 %	0.37 %	2.36 %
Expected dividend yield	— %	— %	— %
Weighted-average option value per share	$ 6.55	$ 0.93	$ 1.00

Utilization of Net Operating Loss Carryforwards

At December 31, 2021, we had net operating loss carryforwards for federal and state tax purposes of approximately $637.9 million and $455.4 million, respectively. At December 31, 2020, we had net operating loss carryforwards for federal and state tax purposes of approximately $551.0 million and $388.5 million, respectively. In addition, we had tax credit carryforwards for federal tax purposes of approximately $23.3 million as of December 31, 2021, which begin to expire in 2022. The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership. In general, if we

experience a greater than 50 percent aggregate change in ownership of certain significant stockholders or groups over a three-year period (a Section 382 ownership change), utilization of our pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Code (and similar state laws). The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the pre-change net operating loss carryforwards before utilization and may be substantial. We have determined that a Section 382 ownership change occurred in 2002 and 2007 resulting in limitations of at least $64,000 and $762,000, respectively, of losses incurred prior to the respective ownership change dates. In addition, we have determined that another Section 382 ownership change occurred in 2013 with our initial public offering, our private placements and other transactions that have occurred since 2007, resulting in a limitation of at least $6.7 million of losses incurred prior to the ownership change date. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Furthermore, under the Tax Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the Tax Act. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2021 and December 31, 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and December 31, 2020, together with the changes in those items in dollars and percentages (in thousands, except percentages):

	Years Ended December 31,		Dollar Change	% Change
	2021	2020	Increase/(Decrease)	
Revenues:				
Contract and grant revenue	$ 1,928	$ 5,274	$ (3,346)	(63.4)%
Licensing revenue	51	98	(47)	(48.0)
Total revenues	1,979	5,372	(3,393)	(63.2)%
Operating expenses:				
Research and development	73,817	36,232	37,585	103.7 %
General and administrative	18,672	13,656	5,016	36.7 %
Acquired in-process research and development	82,890	—	82,890	*
Total operating expenses	175,379	49,888	125,491	251.5 %
Loss from operations	(173,400)	(44,516)	(128,884)	289.5 %
Other income:				
Interest income and other, net	164	994	(830)	(83.5)%
Net loss	$ (173,236)	$ (43,522)	$ (129,714)	298.0 %

***** Not meaningful or not calculable

Contract and Licensing Revenue

For the year ended December 31, 2021, contract and licensing revenue decreased to $2.0 million compared to $5.4 million for the year ended December 31, 2020. The decrease of $3.4 million, or 63.2%, was related to a decrease in reimbursable expenses associated with our development contract with BARDA upon receiving FDA approval for TEMBEXA.

Research and Development Expenses

For the year ended December 31, 2021, our research and development expenses increased to $73.8 million compared to $36.2 million for the year ended December 31, 2020. The increase of $37.6 million, or 103.7%, was primarily related to the following:

- an increase of $20 million related to the success milestone payment to Oncoceutics shareholders upon achievement of a 20% ORR by BICR of ONC01 in recurrent H3 K27M-mutant glioma patients;

- an increase of $14.2 million primarily related to drug manufacturing and clinical trial support of ONC201;
- an increase of $9.5 million in compensation expenses, of which $3.6 million is related to non-cash stock compensation expenses; offset by
- a decrease of $4.5 million in brincidofovir smallpox program expenses with the approval of TEMBEXA in June 2021; and
- a decrease of $2.0 million in DSTAT development expenses primarily related to the conclusion of animal studies.

General and Administrative Expenses

For the year ended December 31, 2021, our general and administrative expenses increased to $18.7 million compared to $13.7 million for the year ended December 31, 2020. The increase of $5.0 million, or 36.7%, was primarily related to the following:

- an increase of $3.6 million in compensation expenses, of which $3.1 million is related to non-cash stock compensation expense; and
- an increase of $1.2 million in consulting, legal, and operational expenses with the growth of the company's infrastructure.

Acquired In-process Research and Development Expenses

In connection with our acquisition of Oncoceutics in January 2021, we recorded a total of $82.9 million of acquired in-process research and development expenses for the year ended December 31, 2021, which included $82.6 million of in-process research and development assets expensed and $0.3 million of transaction costs. We paid consideration including an upfront payment of $25.0 million to Oncoceutics, $43.4 million related to the fair value of the 8,723,769 shares of common stock issued to Oncoceutics, and a $14.0 million promissory note due on the one-year anniversary of the acquisition.

Interest Income and Other, net

For the year ended December 31, 2021, our interest income and other, net was $0.2 million compared to interest income of $1.0 million for the year ended December 31, 2020. The decrease of $0.8 million was largely attributable to amortization of our investment premium balances offsetting interest earned.

Comparison of the Years ended December 31, 2020 and December 31, 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and December 31, 2019, together with the changes in those items in dollars and percentages (in thousands, except for percentages):

	Years Ended December 31,		Dollar Change	% Change
	2020	2019	Increase/(Decrease)	
Revenues:				
Contract and grant revenue	$ 5,274	$ 7,604	$ (2,330)	(30.6)%
Licensing revenue	98	4,915	(4,817)	(98.0)%
Total revenues	5,372	12,519	(7,147)	(57.1)%
Operating expenses:				
Research and development	36,232	42,288	(6,056)	(14.3)%
General and administrative	13,656	21,169	(7,513)	(35.5)%
Acquired in-process research and development	—	65,045	(65,045)	(100.0)%
Total operating expenses	49,888	128,502	(78,614)	(61.2)%
Loss from operations	(44,516)	(115,983)	71,467	(61.6)%
Other income:				
Interest income and other, net	994	3,407	(2,413)	(70.8)%
Net loss	$ (43,522)	$ (112,576)	$ 69,054	(61.3)%

Revenue

For the year ended December 31, 2020, contract revenue decreased to $5.3 million compared to $7.6 million for the year ended December 31, 2019. The decrease of $2.3 million, or 30.6%, was related to a decrease in reimbursable expenses associated with our contract with BARDA. For the year ended December 31, 2020, license revenue decreased to $0.1 million compared to $4.9 million for the year ended December 31, 2019 due to our licensing agreement with SymBio.

Research and Development Expenses

For the year ended December 31, 2020, our research and development expenses decreased to $36.2 million compared to $42.3 million for the year ended December 31, 2019. The decrease of $6.1 million, or 14.3%, was primarily related to the following:

- a decrease of $9.1 million related to the discontinuation of both the oral and IV BCV development programs and the BCV expanded access programs;
- a decrease of $3.5 million in smallpox program expenses;
- a decrease of $2.7 million related to compensation expenses as headcount was reduced as part of the Company’s restructuring activities in May 2019; offset by
- an increase of $9.5 million in DSTAT research and development expenses, consisting of an increase of $5.4 million in clinical trial initiation activities and $4.1 million to conclude animal studies and to develop and manufacture clinical trial material.

General and Administrative Expenses

For the year ended December 31, 2020, our general and administrative expenses decreased to $13.7 million compared to $21.2 million for the year ended December 31, 2019. The decrease of $7.5 million, or 35.5%, was primarily related to the following:

- a decrease of $5.1 million related to compensation expense as headcount was reduced as part of the Company's restructuring activities in May 2019;
- a decrease of $2.2 million related to business development expenses and to out-license BCV for non-smallpox indications; and
- a decrease of $0.2 million in legal fees, other professional fees and operational expenses.

Acquired In-Process Research and Development

We recorded $65.0 million of acquired in-process research and development expenses for the year ended December 31, 2019, which included $30.0 million for an upfront payment to Cantex, $34.9 million related to the fair value of common stock issued to Cantex, and $0.1 million related to Cantex transaction costs, primarily legal and professional fees. There was no expense related to this for the year ended December 31, 2020.

Interest Income and Other, net

For the year ended December 31, 2020, our interest income and other, net was $1.0 million compared to interest income of $3.4 million for the year ended December 31, 2019. The decrease of $2.4 million was largely attributable to lower interest rates and lower cash and investment balances.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2021, we had capital available to fund operations of approximately $90.4 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. We have incurred losses since our inception in 2000 and as of December 31, 2021, we had an accumulated deficit of $885.6 million. We may continue to incur losses for the foreseeable future. The size of our losses will depend, in part, on the rate of future expenditures and our ability to generate revenues.

On August 10, 2020, we entered into an Open Market Sale Agreement℠ (the Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $75 million of shares of our common stock. Sales of our common stock made pursuant to the Jefferies Sales Agreement, if any, will be made under our shelf

registration statement on Form S-3 (File No. 333-244146), which was declared effective by the SEC on August 17, 2020. As of December 31, 2021, we have not sold any shares of our common stock under the Jefferies Sales Agreement.

On January 20, 2021, we entered into an underwriting agreement (the Underwriting Agreement) with Jefferies LLC and Cowen and Company, LLC, as representatives of the several underwriters named therein (collectively, the Underwriters), relating to the issuance and sale of 11,765,000 shares (the Shares) of our common stock. The price to the public in this offering was $8.50 per share, and the Underwriters agreed to purchase the Shares from us pursuant to the Underwriting Agreement at a price of $7.99 per share. Under the terms of the Underwriting Agreement, we granted the Underwriters a 30-day option to purchase up to 1,764,750 additional shares of our common stock at the public offering price. The net proceeds to us from this offering were approximately $107.8 million, as the Underwriters' option to purchase additional shares was exercised in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on January 25, 2021.

On May 6, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, pursuant to which we registered for sale an unlimited amount of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules, This registration statement will remain in effect for up to three years from the date it became effective. As of December 31, 2021, no sales have been made under the automatic shelf registration statement.

On January 31, 2022, we entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank. The Loan Agreement provides for a four-year secured revolving loan facility (the Credit Facility) in an aggregate principal amount of up to $50.0 million. Proceeds from the Credit Facility may be used for working capital and general corporate purposes. Reference the section headed "Recent Developments" for additional information.

On December 22, 2021, BARDA issued a RFP, which confirmed, among other things, BARDA's intent to negotiate a sole source contract with us for the development and procurement of TEMBEXA. The RFP indicates that BARDA intends to contract with us to procure up to 1.7 million treatment courses of a smallpox antiviral. We have responded to the RFP and currently are in active negotiations with BARDA on the price per course of therapy, manufacturing schedule, delivery schedule and quantities. We expect this contract to generate product sales in 2022.

We cannot assure that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs, and any launch and other commercialization expenses for any of our products that may receive marketing approval. We cannot assure you that we will successfully develop or commercialize our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

We believe that our existing cash, cash equivalents, and investments will enable us to fund our current operating expenses and capital requirements for at least the next 12 months. However, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods (in thousands):

	Years Ended December 31,		
Cash sources and uses:	**2021**	**2020**	**2019**
Net cash used in operating activities	$ (99,930)	$ (36,038)	$ (75,181)
Net cash provided by investing activities	(44,091)	64,713	10,631
Net cash provided by financing activities	112,429	1,413	345
Net increase (decrease) in cash and cash equivalents	$ (31,592)	$ 30,088	$ (64,205)

Operating Activities

Net cash used in operating activities of $99.9 million for the year ended December 31, 2021 was primarily the result of our $173.2 million net loss offset by the change in operating asset and liabilities and the add-back of non-cash expenses. The change in operating assets and liabilities includes a increase in accounts payable and accrued liabilities of $7.1 million and a

decrease of $0.3 million in accounts receivable offset by an increase in inventories of $2.8 million and an increase in prepaid expenses and other assets of $2.4 million. Non-cash expenses included add-backs of $43.4 million for the fair value of common stock issued in relation to the Oncoceutics acquisition, $14.0 million for the note payable due on the one-year anniversary of the Oncoceutics acquisition, $12.3 million for stock-based compensation, $0.8 million of amortization of discount/premium on investments, $0.3 million for lease-related amortization and $0.2 million of depreciation of property and equipment.

Net cash used in operating activities of $36.0 million for the year ended December 31, 2020 was primarily the result of our $43.5 million net loss offset by the change in operating assets and liabilities and the add-back of non-cash expenses. The change in operating assets and liabilities includes a decrease in prepaid expenses and other assets of $1.0 million and a decrease of $0.9 million in accounts receivable offset by a decrease in accounts payable and accrued liabilities of $0.2 million. Non-cash expenses included add-backs of $5.6 million for stock-based compensation and $0.4 million of depreciation of property and equipment offset by $0.2 million of amortization of discount/premium on investments.

Net cash used in operating activities of $75.2 million for the year ended December 31, 2019 was primarily the result of our $112.6 million net loss and the change in operating assets and liabilities, offset by the add-back of non-cash expenses. The change in operating assets and liabilities includes a decrease in accounts payable and accrued liabilities of $4.3 million, an increase of $0.9 million in accounts receivable and an increase in prepaid expenses and other assets of $0.8 million. Non-cash expenses included add-backs of $34.9 million for the fair value of common stock issued in relation to the Cantex license agreement, $9.5 million for stock-based compensation, $0.6 million of depreciation of property and equipment, $0.3 million for the loss on disposal of assets, offset by $1.8 million of amortization of discount/premium on investments.

Investing Activities

Net cash provided by investing activities of $44.1 million during the year ended December 31, 2021 was primarily the result of purchases of short-term and long-term investments, offset by maturities and sales of short-term investments. Net cash provided by investing activities of $64.7 million during the year ended December 31, 2020 was primarily the result of maturities and sales of short-term investments, offset by purchases of short-term investments. Net cash provided by investing activities of $10.6 million during the year ended December 31, 2019 was primarily the result of maturities and sales of short-term investments, offset by purchases of short-term investments.

Financing Activities

Net cash provided by financing activities of $112.4 million for the year ended December 31, 2021 was primarily the result of $107.8 million in proceeds from the issuance of common stock and $4.6 million from the exercise of stock options and purchases under the ESPP. Net cash provided by financing activities of $1.4 million for the year ended December 31, 2020 was primarily the result of $1.4 million from the exercise of stock options and purchases under the ESPP. Net cash provided by financing activities of $0.3 million for the year ended December 31, 2019 was primarily the result of $0.4 million from the exercise of stock options and purchases under the ESPP.

Future Funding Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we commercialize TEMBEXA or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Furthermore, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital requirements for at least the next 12 months. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements, or other collaborations, strategic alliances or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be

diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table summarizes our contractual obligations at December 31, 2021 (in thousands):

	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
Operating leases (1)	$ 3,380	$ 637	$ 1,495	$ 1,248	$ —
SPL Supply Purchase Obligation	$ 2,400	$ —	$ 2,400	$ —	$ —
Total	$ 5,780	$ 637	$ 3,895	$ 1,248	$ —

(1) Consists of our corporate headquarters lease encompassing 21,325 square feet of office space that expires in July 2026. Additionally, consists of our laboratory lease encompassing a total of approximately 7,925 square feet which is located in Durham, North Carolina and expires in July 2026.

In addition to the amounts set forth in the table above, we have payment obligations under license agreements that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones. We will be required to make additional payments when certain milestones are achieved and we are obligated to pay royalties based on future product sales. As of December 31, 2021, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. In connection with the development and commercialization of ONC201 and ONC206, in addition to royalties on product sales, we could be required to pay former Oncoceutics securityholders up to an aggregate of $340.0 million in remaining milestone payments, assuming the achievement of all remaining applicable milestone events under the merger agreement. In November 2021, we achieved the BICR milestone and paid the former Oncoceutics securityholders $20 million. In connection with the development and commercialization of DSTAT, in addition to royalties on product sales, we could be required to pay Cantex up to an aggregate of $587.5 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement.

Additionally, we enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination or cancellation within 30 days of notice, and therefore are not included in the table above. We also have agreements with our executive officers that require the funding of specific payments, if certain events occur, such as a change in control or the termination of employment without cause. These potential payment obligations are not included in the table above.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We do not believe that our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents and available-for-sale investments do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations for the years ended December 31, 2021 or 2020.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Chimerix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Chimerix, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Accrued Research and Development Expenses

Description of the Matter	As discussed in Note 1 to the consolidated financial statements, within total accrued liabilities, the Company has recorded $4.6 million of accrued research and development expenses, which includes costs resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with its research and development efforts. As the financial terms of these contracts vary by contract and may result in payment flows that do not match the periods over which materials or services are provided, the Company develops estimates to match expenses with the period in which services and efforts are expended. The Company determines the accrual based on discussions with applicable personnel and outside service providers as to the progress or state of clinical trials or other services completed. Auditing the Company's accrued research and development expenses involves judgment because the timing of vendor invoicing differs from the services actually provided.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls that addressed the information used in, and the identified risks related to, the Company's process for recording accrued research and development expenses, including controls over management's review of the progress of the research and development activities. To evaluate the accrued research and development expenses, our audit procedures included, among others, inspecting the Company's contracts with the research and development related vendors (including pending change orders) and evaluating the underlying data used in the estimate of the services provided. We also corroborated the progress of research and development related activities through inquiry with the Company's project managers and with information obtained directly from third party vendors, as well as tested invoices received from vendors subsequent to the balance sheet date

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2008.
Raleigh, NC
March 1, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Chimerix, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Chimerix, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Chimerix, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Chimerix, Inc. as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Raleigh, NC
March 1, 2022

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,397	$ 46,989
Short-term investments, available-for-sale	72,970	31,973
Accounts receivable	—	340
Inventories	2,760	—
Prepaid expenses and other current assets	4,678	2,356
Total current assets	95,805	81,658
Long-term investments	2,022	—
Property and equipment, net of accumulated depreciation	253	214
Operating lease right-of-use assets	2,404	2,825
Other long-term assets	56	26
Total assets	$ 100,540	$ 84,723
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,788	$ 1,283
Accrued liabilities	13,108	7,250
Note payable	14,000	—
Total current liabilities	29,896	8,533
Lease-related obligations	2,392	2,814
Total liabilities	32,288	11,347
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 86,884,266 and 62,816,039 shares issued and outstanding at December 31, 2021 and 2020, respectively	87	63
Additional paid-in capital	953,782	785,673
Accumulated other comprehensive loss, net	(21)	—
Accumulated deficit	(885,596)	(712,360)
Total stockholders’ equity	68,252	73,376
Total liabilities and stockholders’ equity	$ 100,540	$ 84,723

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

CHIMERIX, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Years Ended December 31,		
	2021	**2020**	**2019**
Revenues:			
Contract and grant revenue	$ 1,928	$ 5,274	$ 7,604
Licensing revenue	51	98	4,915
Total revenues	1,979	5,372	12,519
Operating expenses:			
Research and development	73,817	36,232	42,288
General and administrative	18,672	13,656	21,169
Acquired in-process research and development	82,890	—	65,045
Total operating expenses	175,379	49,888	128,502
Loss from operations	(173,400)	(44,516)	(115,983)
Other income:			
Interest income and other, net	164	994	3,407
Net loss	(173,236)	(43,522)	(112,576)
Other comprehensive loss:			
Unrealized (loss) gain on investments, net	(21)	(35)	127
Comprehensive loss	$ (173,257)	$ (43,557)	$ (112,449)
Per share information:			
Net loss, basic and diluted	$ (2.04)	$ (0.70)	$ (2.03)
Weighted-average shares outstanding, basic and diluted	84,930,255	62,183,947	55,501,973

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

CHIMERIX, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2018	50,735,279	$ 51	$ 733,907	$ (92)	$ (556,262)	$ 177,604
Share-based compensation	—	—	9,528	—	—	9,528
Exercise of stock options	19,284	—	43	—	—	43
Employee stock purchase plan purchases	209,075	—	326	—	—	326
RSU stock issuance	626,375	1	(1)	—	—	—
Issuance of common stock, net of issuance costs	10,000,000	10	34,890	—	—	34,900
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	127	—	127
Net loss	—	—	—	—	(112,576)	(112,576)
Total comprehensive loss						(112,449)
Balance, December 31, 2019	61,590,013	$ 62	$ 778,693	$ 35	$ (668,838)	$ 109,952
Share-based compensation	—	—	5,568	—	—	$ 5,568
Exercise of stock options	409,988	1	986	—	—	$ 987
Employee stock purchase plan purchases	337,072	—	426	—	—	$ 426
RSU stock issuance	478,966	—	—	—	—	$ —
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	(35)	—	$ (35)
Net loss	—	—	—	—	(43,522)	$ (43,522)
Total comprehensive loss						(43,557)
Balance, December 31, 2020	62,816,039	$ 63	$ 785,673	$ —	$ (712,360)	$ 73,376
Share-based compensation	—	—	12,260	—	—	$ 12,260
Exercise of stock options	841,775	1	3,830	—	—	$ 3,831
Employee stock purchase plan purchases	542,931	1	754	—	—	$ 755
RSU stock issuance	430,002	—	—	—	—	$ —
Issuance of common stock related to asset acquisition	8,723,769	9	43,436	—	—	$ 43,445
Issuance of common stock, net of issuance costs	13,529,750	13	107,829	—	—	$ 107,842
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	(21)	—	$ (21)
Net loss	—	—	—	—	(173,236)	$ (173,236)
Total comprehensive loss						(173,257)
Balance, December 31, 2021	86,884,266	$ 87	$ 953,782	$ (21)	$ (885,596)	$ 68,252

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

CHIMERIX, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net loss	$ (173,236)	$ (43,522)	$ (112,576)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	167	402	564
Amortization of discount/premium on investments	846	(190)	(1,842)
Share-based compensation	12,260	5,568	9,528
Fair value of common stock issued related to asset acquisition	43,445	—	—
Note payable related to asset acquisition	14,000	—	—
Fair value of common stock issued for license agreement	—	—	34,900
(Gain)/Loss on disposition of assets	—	(10)	264
(Gain)/Loss on sale of investments	(2)	(4)	31
Lease-related amortization	301	(14)	(76)
Changes in operating assets and liabilities:			
Accounts receivable	340	893	(903)
Inventories	(2,760)	—	—
Prepaid expenses and other assets	(2,352)	1,025	(777)
Accounts payable and accrued liabilities	7,061	(186)	(4,294)
Net cash used in operating activities	(99,930)	(36,038)	(75,181)
Cash flows from investing activities:			
Purchases of property and equipment	(207)	(58)	(158)
Purchases of short-term investments	(105,355)	(73,978)	(167,528)
Purchases of long-term investments	(9,594)	—	—
Proceeds from sales of short-term investments	4,207	17,287	13,117
Proceeds from maturities of short-term investments	66,858	121,452	165,200
Proceeds from sale of property and equipment	—	10	—
Net cash (used in) provided by investing activities	(44,091)	64,713	10,631
Cash flows from financing activities:			
Proceeds from exercise of stock options	3,831	987	43
Proceeds from employee stock purchase plan	755	426	325
Proceeds from issuance of common stock, net of commissions	107,843	—	—
Payments of deferred offering costs	—	—	(23)
Net cash provided by financing activities	112,429	1,413	345
Net (decrease) increase in cash and cash equivalents	(31,592)	30,088	(64,205)
Cash and cash equivalents:			
Beginning of period	46,989	16,901	81,106
End of period	$ 15,397	$ 46,989	$ 16,901
Supplemental disclosure of cash flow information			
Non-cash purchases of property and equipment	$ —	$ 18	$ —

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

Note 1. The Business and Summary of Significant Accounting Policies

Description of Business

Chimerix is a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. In June 2021, the U.S. Food and Drug Administration (FDA) approved TEMBEXA (brincidofovir) for the treatment of smallpox as a medical countermeasure. Our two most advanced clinical-stage development programs are ONC201 and dociparstat sodium (DSTAT). ONC201 is in development for recurrent H3 K27M-mutant glioma. DSTAT is in Phase 3 development as a potential first-line therapy in acute myeloid leukemia (AML).

Basis of Presentation

The consolidated financial statements include the accounts of the Company, and its wholly owned subsidiaries. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the Company's consolidated financial statements requires estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Although these estimates are based on knowledge of current events and actions the Company may undertake in the future, actual results may ultimately differ from these estimates and assumptions.

Reclassifications

Certain prior period amounts in the accompanying consolidated financial statements have been reclassified to conform to the current year presentation. These reclassifications had no effect on previously reported net income or stockholders' equity (deficit).

Cash and Cash Equivalents

The Company considers any highly liquid instrument with an original maturity of three months or less at acquisition to be a cash equivalent. Cash equivalents consist of money market funds.

Investments

Investments consist primarily of commercial paper, corporate bonds, and U.S. Treasury securities. The Company invests in high-credit quality investments in accordance with its investment policy which minimizes the probability of loss.

Available-for-sale debt securities are carried at fair value as determined by quoted market prices, with the unrealized gains and losses, net of tax, reported as a separate component of stockholders' equity. Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis in interest income and other, net. For the year ended December 31, 2021, approximately $2,000 of realized gains were reclassified from accumulated other comprehensive loss, net in the Consolidated Balance Sheets to interest income and other, net in the Consolidated Statements of Operations and Comprehensive Loss. Investments with original maturities beyond three months at the date of purchase and which mature on, or less than twelve months from, the balance sheet date are classified as short-term. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term.

The Company periodically reviews available-for-sale debt securities for other-than-temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company evaluates, among other things, the duration and extent to which the fair value of a security is less than its cost; the financial condition of the issuer and any changes thereto; and the Company's intent to sell, or whether it will more likely than not be required to sell, the security before recovery of its amortized cost basis. The Company does not intend to sell, and is not likely to be required to sell, the available-for-sale debt securities in an unrealized loss position before recovery of the amortized cost bases of the debt securities, which may be maturity. Any such declines in value judged to be other-than-temporary on available-for-sale debt securities are reported in other-than-temporary impairment of investment.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, short-term investments, long-term investments and accounts receivable. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding its cash and cash equivalents to the extent of amounts recorded on the balance sheets. Accounts receivable represent amounts due from an agency of the federal government.

Accounts Receivable

Accounts receivable at December 31, 2020 consisted of amounts billed under the Company's contract with the Biomedical Advanced Research and Development Authority (BARDA). Receivables under the BARDA contract are recorded as qualifying research activities are conducted and invoices from the Company's vendors are received. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs and the current status of all receivables. The Company does not accrue interest on trade receivables. If accounts become uncollectible, they will be written off through a charge to the allowance for doubtful accounts. The Company has not recorded a charge to allowance for doubtful accounts as management believes all receivables are fully collectible.

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments, including accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of such instruments.

For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates and are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, fair value measurements cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the calculated current or future fair values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

The Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. The determination of where an asset or liability falls in the hierarchy requires significant judgment. These levels are:

- *Level 1* — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- *Level 2* — Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and models for which all significant inputs are observable, either directly or indirectly.
- *Level 3* — Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

At December 31, 2021 and December 31, 2020, the Company had cash equivalents, including money market funds, and short-term investments, including U.S. Treasury securities, whose value is based on using quoted market prices. At December 31, 2021, the Company had long-term investments, including U.S. Treasury securities, whose value is based on using quoted market prices. Accordingly, these securities are classified as Level 1.

At December 31, 2021, the Company had short-term investments, including commercial paper, corporate bonds and U.S. Treasury securities. At December 31, 2020, the Company had short-term investments including corporate bonds. As quoted prices are not available for these securities, they are valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security's credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

There was no material re-measurement to fair value of financial assets and liabilities that are not measured at fair value on a recurring basis. For additional information regarding the Company's investments, please refer to Note 2, "Investments."

Below is a table that presents information about certain assets measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements December 31, 2021			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 11,841	$ 11,841	$ —	$ —
Total cash equivalents	11,841	11,841	—	—
Short-term investments				
U.S. Treasury securities	7,517	2,523	4,994	—
Commercial paper	34,887	—	34,887	—
Corporate bonds	30,566	—	30,566	—
Total short-term investments	72,970	2,523	70,447	—
Long-term investments				
U.S. Treasury securities	2,022	2,022	—	—
Total long-term investments	2,022	2,022	—	—
Total assets	$ 86,833	$ 16,386	$ 70,447	$ —

	Fair Value Measurements December 31, 2020			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 1,503	$ 1,503	$ —	$ —
Total cash equivalents	1,503	1,503	—	—
Short-term investments				
U.S. Treasury securities	28,715	28,715	—	—
Corporate bonds	3,258	—	3,258	—
Total short-term investments	31,973	28,715	3,258	—
Total assets	$ 33,476	$ 30,218	$ 3,258	$ —

Inventories

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs. We begin capitalization of these inventory related costs once regulatory approval is obtained. We primarily use actual costs to determine our cost basis for inventories.

At December 31, 2021, our inventory is related to TEMBEXA, which is being manufactured for the treatment of smallpox and potential delivery to the Strategic National Stockpile (SNS) for the U.S. government and other government agencies. TEMBEXA was approved by the FDA on June 4, 2021, at which time we began to capitalize inventory costs associated with TEMBEXA. Prior to FDA approval of TEMBEXA, all costs related to the manufacturing of TEMBEXA were charged to research and development expense in the period incurred as there was no alternative future use.

We value our inventories at the lower of cost or estimated net realizable value. We determine the cost of its inventories, which includes amounts related to materials, manufacturing costs, shipping and handling costs on a first-in, first-out (FIFO) basis.

Work-in-process includes all inventory costs prior to packaging and labelling, including raw material, active product ingredient, and drug product. Finished goods include packaged and labelled products. Our inventories at December 31, 2021, consisted of $2.8 million of work-in-process and no finished goods.

Our assessment of market value requires the use of estimates regarding the net realizable value of its inventory balances, including an assessment of excess or obsolete inventory. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires it to utilize judgment. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for its products, product expiration dates and current sales levels. Our assumptions of future demand for its products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. In addition, our inventory may experience expiration of its shelf-life stability. During the twelve months ended December 31, 2021, we did not record a reserve for inventory as we assume TEMBEXA will be sold to the US government under a procurement contract with Biomedical Advanced Research and Development Authority (BARDA) or could be sold to other governmental agencies. Should no procurement contract be secured in the future, we may reserve part or all of our inventory balance, which would be included in cost of sales.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2021	**2020**
Prepaid research and development expenses	$ 1,726	$ 1,167
Interest receivable	348	104
Prepaid insurance	450	354
Other prepaid expenses and current assets	2,154	731
Total prepaid expenses and other current assets	$ 4,678	$ 2,356

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from three to five years. Leasehold improvements are amortized over the shorter of the useful life of the asset or the term of the related lease. Maintenance and repairs are charged against expense as incurred.

Impairment of Property and Equipment

The Company evaluates property and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. For the twelve months ended December 31, 2021 and 2020, no such write-downs have occurred.

Leases

At the inception of an arrangement, we determine if an arrangement is, or contains, a lease based on the unique facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease we (i) identify lease and non-lease components, (ii) determine the consideration in the contract, (iii) determine whether the lease is an operating or financing lease; and (iv) recognize lease right-of-use (ROU) assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, we use our incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Most leases include options to renew and, or, terminate the lease, which can impact the lease term. The exercise of these options is at our discretion and we do not include any of these options within the expected lease term as we are not reasonably certain we will exercise these options.

The current portion of our operating lease liabilities is included in accrued liabilities and the long-term portion is included in lease-related obligations.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued compensation	$ 5,491	$ 4,473
Accrued research and development expenses	4,642	1,375
Accrued legal expenses	359	651
Other accrued liabilities	2,616	751
Total accrued liabilities	$ 13,108	$ 7,250

Revenue Recognition

Policy

The Company's revenues generally consist of (i) contract revenue - revenue generated under federal contracts, and (ii) collaboration and licensing revenue - revenue related to non-refundable upfront fees, royalties and milestone payments earned under license agreements. Revenue is recognized in accordance with the criteria outlined in Accounting Standards Codification (ASC) 606 issued by the Financial Accounting Standards Board (FASB). Following this accounting pronouncement, a five-step approach is applied for recognizing revenue, including (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the entity satisfies a performance obligation.

Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, the Company entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. Under the contract, the Company received $72.5 million in expense reimbursement and $4.6 million in fees over the performance of 1 base segment and 4 option segments. Exercise of each option segment was solely at the discretion of BARDA. The Company assessed the services in accordance with the authoritative guidance and concluded that there was a potential of 5 separate contracts (1 base segment and four option segments) within this agreement, each of which had a single performance obligation. All option segments (one through four) were exercised, as well as the base segment. The transaction price for each segment, based on the transaction price as defined in each segment contract, was allocated to the single performance obligation for each contract. The transaction price was recognized over time by measuring the progress toward complete satisfaction of the performance obligation. For reimbursable expenses, this occurred as qualifying research activities were conducted based on invoices from company vendors. For the fixed fee, the progress toward complete satisfaction was estimated based on the costs incurred to date relative to the total estimated costs per the terms of each contract. The Company typically invoiced BARDA monthly as costs were incurred. Any amounts received in advance of performance were recorded as deferred revenue until earned. The base segment and first option segment were completed prior to adoption of ASC 606. The second and third option segments were completed on August 20, 2020. The fourth option segment was completed on September 1, 2021 and the contract has expired in accordance with its terms.

Grant Revenue

Grant revenue under cost-plus-fixed-fee grants from the federal government and private foundations is recognized as allowable costs are incurred and fees are earned. As a result of its acquisition of Oncoceutics, Inc. (Oncoceutics), the Company became the beneficiary of two federal grant programs and two grant programs with private foundations, of which the federal grant programs ended in the third quarter of 2021. At December 31, 2021, the Company has a deferred revenue balance of $0.2 million related to these grants. Additionally, for the twelve months ended months ended December 31, 2021, the Company recognized $0.4 million of grant revenue related to these grants.

SymBio Pharmaceuticals

On September 30, 2019, the Company entered into a license agreement with SymBio Pharmaceuticals Limited (SymBio) under which the Company granted SymBio exclusive worldwide rights to develop, manufacture and commercialize BCV for all human indications, excluding the prevention and treatment of orthopoxviruses, including smallpox. The Company assessed the agreement in accordance with the authoritative guidance and concluded that the SymBio contract includes multiple performance obligations. The SymBio contract has one fixed transaction amount of a $5.0 million upfront payment received in October 2019 and several variable transaction amounts, up to $180.0 million, due to the Company at certain regulatory and commercial milestones, along with low double-digit percent royalties based on net sales of BCV. All variable transaction amounts are fully constrained, therefore the allocated transaction price is $5.0 million. The majority of the transaction price of the contract has been allocated to the combined performance obligation of the granting of the license to BCV and associated technology transfer which was recognized when the technology transfer was completed in the fourth quarter of 2019. The revenue from regulatory and commercial milestones and royalties from net sales will be recognized upon the occurrence of the triggering events or when those transaction amounts are no longer fully constrained.

Research and Development Prepaids and Accruals

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with its research and development efforts. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts.

The Company's objective is to reflect the appropriate research and development expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of its research and development efforts. The Company determines prepaid and accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of clinical trials, or other services completed. The Company adjusts its rate of research and development expense recognition if actual results differ from its estimates. The Company makes estimates of its prepaid and accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through December 31, 2021, there had been no material adjustments to the Company's prior period estimates of prepaid and accruals for research and development expenses. The Company's research and development prepaids and accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Research and Development Expenses

Major components of research and development costs include cash compensation, stock-based compensation, preclinical studies, clinical trial and related clinical manufacturing, drug development, materials and supplies, legal, regulatory compliance, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf. Research and development costs, including upfront fees and milestones paid to contract research organizations, are expensed as goods are received or services rendered. Costs incurred in connection with clinical trial activities for which the underlying nature of the activities themselves do not directly relate to active research and development, such as costs incurred for market research and focus groups linked to clinical strategy as well as costs to build the Company's brand, are not included in research and development costs but are reflected as general and administrative costs.

Interest Income and Other, Net

Interest income and other, net consists primarily of interest earned on our cash, cash equivalents and short-term and long-term investments.

Income Taxes

Deferred tax assets and liabilities are determined based on differences between the financial and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when the Company determines that it is more likely than not that

some portion of a deferred tax asset will not be realized. The Company has incurred operating losses from April 7, 2000 (inception) through December 31, 2021, and therefore has not recorded any current provision for income taxes.

Additionally, the Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement. Accordingly, the Company establishes reserves for uncertain tax positions.

The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income (GILTI), states that an entity can make an accounting policy election to either recognized deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI as a period expense in the year the tax is incurred.

Share-Based Compensation

The Company measures and recognizes compensation expense for all share-based payment awards made to employees and directors, including employee stock options, restricted stock units and the employee stock purchase plan purchase rights, based on estimated fair values. The fair value of employee stock options and employee stock purchase plan purchase rights is estimated on the grant date using the Black-Scholes valuation model. The grant-date fair value for restricted stock units is based upon the market price of the Company's common stock on the date of the grant. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite service periods. For performance-based awards compensation cost is recognized when it is probable that the performance criteria will be met.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate forfeitures and records share-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. For the years ended December 31, 2021, 2020 and 2019, the Company applied a forfeiture rate based on the Company's historical forfeitures.

401(k) Plan

The Company maintains a defined contribution employee retirement plan (401(k) plan). For the years ended December 31, 2021, 2020 and 2019, the Company recognized expenses for matching contributions of $0.4 million, $0.3 million and $0.3 million, respectively.

Basic and Dilutive Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of warrants to purchase common stock, non-vested restricted stock, stock options, and employee stock purchase plan purchase rights. Diluted net loss per share of common stock is computed by dividing net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of warrants to purchase common stock, non-vested restricted stock, stock options, and employee stock purchase plan purchase rights outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted loss per share of common stock at December 31, 2021, 2020 and 2019.

The calculation of weighted-average diluted shares outstanding excludes the dilutive effect of non-vested restricted stock, stock options to purchase common stock, and employee stock purchase plan purchase rights as the impact of such items are anti-dilutive during periods of net loss. Potential common shares excluded from the calculations were 4,672,859, 1,162,161, and 1,571,356, for the years ended December 31, 2021, 2020 and 2019, respectively.

Segments

The Company operates in only one segment, pharmaceuticals.

Impact of Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach on expected losses to estimate credit losses on certain financial instruments, including trade receivables and available-for-sale debt securities. The new guidance was originally due to become effective for the Company beginning in the first quarter of 2020, however the FASB in November 2019 issued ASU 2019-10 which moved the effective date for smaller reporting companies to the first quarter of 2023. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements.

Note 2. Investments

The following tables summarize the Company's short-term and long-term debt investments (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 30,571	$ 2	$ (7)	$ 30,566
Commercial paper	34,890	2	(5)	34,887
U.S. Treasury securities	9,552	—	(13)	9,539
Total investments	$ 75,013	$ 4	$ (25)	$ 74,992

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 3,256	$ 2	$ —	$ 3,258
U.S. Treasury securities	28,717	1	(3)	28,715
Total investments	$ 31,973	$ 3	$ (3)	$ 31,973

The following tables summarize the Company's debt investments with unrealized losses, aggregated by investment type and the length of time that individual investments have been in a continuous unrealized loss position (in thousands, except number of securities):

	December 31, 2021					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 28,362	$ (7)	$ —	$ —	$ 28,362	$ (7)
Commercial paper	8,991	(5)	—	—	8,991	(5)
U.S. Treasury securities	9,539	(13)	—	—	9,539	(13)
Total	$ 46,892	$ (25)	$ —	$ —	$ 46,892	$ (25)
Number of securities with unrealized losses		18		—		18

	December 31, 2020					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. Treasury securities	$ 16,598	$ (3)	$ —	$ —	$ 16,598	$ (3)
Total	$ 16,598	$ (3)	$ —	$ —	$ 16,598	$ (3)
Number of securities with unrealized losses		6		—		6

The following table summarizes the scheduled maturity for the Company's debt investments at December 31, 2021 (in thousands):

	December 31, 2021
Maturing in one year or less	$ 72,970
Maturing after one year through two years	2,022
Total debt investments	$ 74,992

Note 3. Property and Equipment

Property and equipment, net of accumulated depreciation consisted of the following (in thousands):

	December 31,	
	2021	2020
Lab equipment	$ 2,341	$ 2,323
Leasehold improvements	1,713	1,584
Computer equipment	817	1,207
Office furniture and equipment	520	520
Property and equipment	5,391	5,634
Less accumulated depreciation	(5,138)	(5,420)
Property and equipment, net of accumulated depreciation	$ 253	$ 214

Note 4. Commitments and Contingencies

Leases

The Company leases its facilities under long-term operating leases that expire at various dates through 2026. The Company generally has options to renew lease terms on its facilities, which may be exercised at the Company's sole discretion. In addition, certain lease arrangements may be terminated prior to their original expiration date at the Company's discretion. The Company evaluates renewal and termination options at the lease commencement date to determine if it is reasonably certain to exercise the option and has concluded on all operating leases that it is not reasonably certain that any options will be exercised. The weighted-average remaining lease term for the Company's operating leases as of December 31, 2021 was 4.58 years.

Expense related to leases is recorded on a straight-line basis over the lease term. Lease expense under operating leases, including common area maintenance fees, totaled approximately $0.7 million and $0.7 million for the twelve months ended December 31, 2021 and 2020, respectively.

The discount rate implicit within the Company's leases is generally not determinable and therefore the Company determines the discount rate based on its incremental borrowing rate based on the information available at commencement date. As of December 31, 2021, the operating lease liabilities reflect a weighted-average discount rate of 7.89%.

The following table sets forth the operating lease right-of-use assets and liabilities as of December 31, 2021 (in thousands):

Assets	
Operating Lease Right-of-Use Assets	$ 2,404
Liabilities	
Operating Lease Short-term Liabilities (recorded within Accrued liabilities)	$ 432
Operating Lease Long-term Liabilities (recorded within Lease-related obligations)	2,392
Total Operating Lease Liabilities	$ 2,824

Operating lease payments over the remainder of the lease terms are as follows (in thousands):

Years Ending December 31,	As of December 31, 2021
2022	637
2023	736
2024	759
2025	781
2026	467
Total future minimum rental payments	$ 3,380
Less amount of lease payments representing interest	556
Total present value of lease payments	$ 2,824

For the twelve months ended December 31, 2021 and 2020, the Company made lease payments of approximately $0.5 million and $0.7 million, respectively, which are included in operating cash flows.

Sublease

The Company subleased 3,537 square feet of its office space under a non-cancelable operating lease that expired February 2021. For the twelve months ended December 31, 2021 and 2020, the Company recognized approximately $12,000 and $71,000 of income in Interest income and other, net on the Consolidated Statement of Operations and Comprehensive Loss, respectively. As this lease has terminated, there are no future minimum rentals payments to be received.

Significance of Revenue Source

The Company is the recipient of federal research contract funds from BARDA. Periodic audits are required under the grant and contract agreements and certain costs may be questioned as appropriate under the agreements. At December 31, 2021 and 2020, the Company had recorded a $52,000 and $38,000 provision for potential refundable amounts, respectively.

Note 5. Stockholders' Equity (Deficit)

Common Stock

The Company's common stock consists of 200 million authorized shares at December 31, 2021 and 2020, and 86.9 million and 62.8 million shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively.

Shares Reserved for Future Issuance

The Company has reserved shares of common stock for future issuances as follows:

	December 31,	
	2021	2020
For exercise of outstanding common stock options	11,649,594	8,906,271
For delivery upon vesting of outstanding restricted stock units	896,222	1,133,049
For future equity awards under the 2013 Equity Incentive Plan	2,076,923	3,342,555
For future purchases under the 2013 Employee Stock Purchase Plan	2,298,817	2,419,213
Total shares of common stock reserved for future issuances	16,921,556	15,801,088

Stock Options

The Company maintains a 2013 Equity Incentive Plan (the 2013 Plan). The 2013 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company and its affiliates. Additionally, the 2013 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants. The number of shares of common stock reserved for issuance under the 2013 Plan will automatically increase on January 1 of

each year, continuing through and including January 1, 2023, by 4.0% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors.

The Company estimates the fair value of its share-based awards to employees, directors and consultants using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. For stock options, the Company uses historical volatility data to estimate the volatility of our common stock price and historical exercise data to estimate the expected life. The risk-free interest rates for the periods within the expected life of the option are based on the U.S. Treasury instrument with a life that is similar to the expected life of the option grant. The Company has never paid, and does not expect to pay, dividends in the foreseeable future.

The following table illustrates the assumptions for the Black-Scholes model used in determining the fair value of the stock options granted:

	Years Ended December 31,		
	2021	2020	2019
Expected volatility	95.84 %	93.24 %	88.77 %
Expected term (in years)	6.0	6.0	6.0
Weighted-average risk-free interest rate	0.71 %	1.24 %	2.42 %
Expected dividend yield	— %	— %	— %
Weighted-average fair value per option	$ 6.67	$ 1.78	$ 1.71

A summary of activity related to the Company's stock options is as follows:

	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Total Intrinsic Value
Balance, December 31, 2019	8,390,304	$ 8.36	7.47	
Granted	3,508,080	2.37	—	
Exercised	(409,988)	2.41	—	
Forfeited	(2,575,125)	11.80	—	
Balance, December 31, 2020	8,913,271	$ 5.28	7.52	
Granted	3,903,750	8.74	—	
Exercised	(909,997)	4.69	—	
Forfeited	(257,432)	15.12	—	
Balance, December 31, 2021	11,649,592	$ 6.27	7.65	$ 25,754
Exercisable at December 31, 2021	6,133,945	$ 6.62	6.83	$ 15,293
Vested or expected to vest at December 31, 2021	10,855,470	$ 6.28	7.58	$ 24,368

As of December 31, 2021, there was approximately $19.6 million of total unrecognized compensation cost related to non-vested stock options granted under the 2013 Plan. That compensation cost is expected to be recognized over a weighted-average period of approximately 2.78 years.

Other information regarding the Company's stock options is as follows (in thousands, except per share data):

	Years Ended December 31,		
	2021	2020	2019
Weighted-average grant-date fair value per share of options granted	$ 6.67	$ 1.78	$ 1.71
Total intrinsic value of options exercised	$ 3,496	$ 355	$ 10
Total fair value of shares vested	$ 8,642	$ 4,188	$ 6,798

The following table summarizes, at December 31, 2021, by price range: (1) for stock option awards outstanding under the 2013 Plan, the number of stock option awards outstanding, their weighted-average remaining life and their weighted-average exercise price; and (2) for stock option awards exercisable under the 2013 Plan, the number of stock option awards exercisable and their weighted-average exercise price:

	Outstanding			Exercisable	
Exercise Price Range ($)	Number	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Number	Weighted-Average Exercise Price
1.37 to 7.57	7,273,390	7.55	$ 2.89	4,424,385	$ 2.97
7.58 to 8.06	814,900	6.13	7.98	617,400	8.02
8.07 to 18.75	3,162,602	8.86	9.61	693,460	10.69
18.76 to 53.74	398,700	3.06	37.86	398,700	37.86
1.37 to 53.74	11,649,592	7.65	$ 6.27	6,133,945	$ 6.62

In April 2019, the Company granted stock options covering a total of 1,750,000 shares in connection with the hiring of its Chief Executive Officer and Chief Business Officer. These grants were non-qualified stock options, have a 10-year term and will vest over four years, with one-fourth vesting on the one-year anniversary of the grant date and remaining three-fourths vesting over the following three years in equal monthly installments. These stock options are subject to the terms of the 2013 Plan, but were granted outside of the 2013 Plan, as they constituted inducement grants in accordance with Nasdaq Stock Market rules.

Employee Stock Purchase Plan

In February 2013, the Company's board of directors adopted the 2013 Employee Stock Purchase Plan (ESPP), which was subsequently ratified by stockholders and became effective in April 2013. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward the Company's success and that of its affiliates. The ESPP initially authorized the issuance of 704,225 shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2014 through January 1, 2023 by the least of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 422,535 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986. The common stock reserved for future issuance under the ESPP was automatically increased by an additional 422,535 shares on January 1, 2020 and 2021, bringing the total number of shares of common stock that may be purchased under the ESPP to 3,493,866 and 3,916,401, respectively.

The Company has reserved a total of 3,916,401 shares of common stock to be purchased under the ESPP, of which 2,298,817 and 2,419,213 shares remained available for purchase at December 31, 2021 and 2020, respectively. Eligible employees may authorize an amount up to 15% of their salary to purchase common stock at the lower of a 15% discount to the beginning price of their offering period or a 15% discount to the ending price of each six-month purchase interval. The ESPP also provides for an automatic reset feature to start participants on a new twenty-four-month participation period in the event that the common stock market value on a purchase date is less than the common stock value on the first day of the twenty-four month offering period. The Company issued 542,931 and 337,072 shares of common stock pursuant to the ESPP for the year ended December 31, 2021 and 2020, respectively. Compensation expense for purchase rights under the ESPP related to the purchase discount and the "look-back" option were determined using a Black-Scholes option pricing model.

The following table illustrates the assumptions for the Black-Scholes model used in determining the fair value of the ESPP purchase rights:

	Years Ended December 31,		
	2021	2020	2019
Expected volatility	97.54 %	75.39 %	57.22 %
Expected term (in years)	0.71	1.28	1.23
Weighted-average risk-free interest rate	0.25 %	0.37 %	2.36 %
Expected dividend yield	— %	— %	— %
Weighted-average option value per share	$ 6.55	$ 0.93	$ 1.00

As of December 31, 2021, the Company had a liability of $0.4 million representing employees' contributions to the ESPP.

Restricted Stock Units

For the years ended December 31, 2021 and 2020, the Company issued RSUs to certain employees and consultants which vest based on service criteria. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The grant date fair value for RSUs is based upon the market price of the Company's common stock on the date of the grant. The fair value is then amortized to compensation expense over the requisite service period or vesting term. For the years ended December 31, 2021 and 2020, the Company issued 430,002 and 478,966 shares of common stock pursuant to the vesting of RSUs, respectively.

A summary of activity related to the Company's RSUs is as follows:

	Number of Restricted Stock Units Outstanding	Weighted-Average Grant-Date Fair Value
Balance, December 31, 2020	1,133,049	$ 2.61
Granted	216,875	9.28
Share issuance	(430,002)	2.88
Forfeited	(23,700)	6.80
Balance, December 31, 2021	896,222	$ 3.98

The total unrecognized compensation cost related to the non-vested RSUs as of December 31, 2021 was $2.3 million and will be recognized over a weighted average period of approximately 2.39 years.

Stock-based Compensation

For awards with only service conditions and graded-vesting features, the Company recognizes compensation expense on a straight-line basis over the requisite service period. Total stock-based compensation expense was as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Income Statement Classification:			
Research and development expense	$ 6,611	$ 2,969	$ 4,089
General and administrative expense	5,649	2,599	5,439
Total stock-based compensation expense	$ 12,260	$ 5,568	$ 9,528

Cash received from exercises under all share-based payment arrangements for 2021, 2020 and 2019 was $4.6 million, $1.4 million and $0.4 million, respectively. There was no actual tax benefit realized for the tax deductions from exercises of the share-based payment arrangements during 2021, 2020 or 2019.

On February 5, 2019, Dr. M. Michelle Berrey, the Company's then President and Chief Executive Officer, resigned. The Company entered into a severance agreement with Dr. Berrey that provides for severance benefits to her in connection with her resignation. Among other benefits, Dr. Berrey received accelerated vesting of her outstanding stock options and RSUs as if she

had continued service for an additional 15-month period. In addition, Dr. Berrey's vested options were modified to extend her exercise period to May 5, 2020. The Company recorded a charge of $1.8 million to compensation expense on the date of her resignation related to the acceleration of vesting and the modifications of her outstanding stock options and RSUs.

In May 2019, related to the Company's reduction in workforce further discussed in Note 8, certain outstanding stock option and RSU grants received accelerated vesting as if the service period of the terminated employee continued for an additional 12-month period. In addition, certain vested options were modified to extend their exercise period for 12 months. The Company recorded a charge of $0.7 million to compensation expense on the date of the reduction in workforce related to the acceleration of vesting and the modifications of the outstanding stock options and RSUs.

At-The-Market Equity Offering

On August 10, 2020, we entered into an Open Market Sale Agreement[SM] (the Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $75 million of shares of our common stock. Sales of our common stock made pursuant to the Jefferies Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 (File No. 333-244146), which was declared effective by the SEC on August 17, 2020. We have not sold any shares of our common stock under the Jefferies Sales Agreement.

On May 6, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, pursuant to which we registered for sale an unlimited amount of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules, This registration statement will remain in effect for up to three years from the date it became effective. As of December 31, 2021, no sales have been made under the automatic shelf registration statement.

Public Offering of Common Stock

On January 20, 2021, the Company entered into an underwriting agreement (the Underwriting Agreement) with Jefferies LLC and Cowen and Company, LLC, as representatives of the several underwriters named therein (collectively, the Underwriters), relating to the issuance and sale of 11,765,000 shares (the Shares) of the Company's common stock. The price to the public in this offering was $8.50 per share, and the Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of $7.99 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to 1,764,750 additional shares of the Company's common stock at the public offering price. The net proceeds to the Company from this offering were approximately $107.8 million, as the Underwriters' option to purchase additional shares was exercised in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering closed on January 25, 2021.

Note 6. Income Taxes

No income tax expense or benefit has been recorded for the years ended December 31, 2021, 2020 or 2019. This is due to the establishment of a valuation allowance against the deferred tax assets generated during those periods. At December 31, 2021, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the net deferred tax assets have been fully reserved.

A reconciliation of the difference between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows for the years ended December 31, 2021, 2020, and 2019 (in thousands, except percentages):

	2021		2020		2019	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	$ (36,379)	21.0 %	$ (9,140)	21.0 %	$ (23,641)	21.0 %
State income taxes	(8,060)	4.7 %	(138)	0.3 %	(1,596)	1.4 %
Research and development credits	(1,565)	0.9 %	(1,088)	2.5 %	(1,190)	1.1 %
In process R&D	26,395	(15.2)%	—	— %	—	— %
Permanent items	711	(0.4)%	505	(1.2)%	696	(0.6)%
Provision to return adjustments	126	(0.1)%	81	(0.2)%	937	(0.8)%
Effect of change in federal tax rate	—	— %	—	— %	—	— %
Effect of change in state tax rate	3,478	(2.0)%	1,139	(2.6)%	(117)	0.1 %
Removal of excess tax benefit	—	— %	—	— %	—	— %
Increase in unrecognized tax benefits	439	(0.3)%	272	(0.6)%	298	(0.3)%
Current year forfeitures	435	(0.3)%	4,026	(9.2)%	—	— %
Change in valuation allowance	14,420	(8.3)%	4,343	(10.0)%	24,613	(21.9)%
Net benefit	$ —	— %	$ —	— %	$ —	— %

The components of deferred tax assets and liabilities at December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Domestic net operating loss carryforwards	$ 138,548	$ 123,381
Research and development expenses	1,191	293
Capitalized Section 174 expenses	—	—
License fees	14,131	12,556
Research and development credits	17,738	15,498
Capital loss carryforwards	484	403
Accrued bonuses	888	943
Share-based compensation	4,885	3,541
Other	1,457	961
Total gross deferred tax assets	179,322	157,576
Valuation allowance	(178,705)	(156,973)
Total deferred tax assets	617	603
Deferred tax liabilities:		
Right-of-use asset	(617)	(603)
Total deferred tax liabilities	(617)	(603)
Total deferred tax assets and liabilities, net	$ —	$ —

At December 31, 2021, the Company had net operating loss carryforwards for federal and state tax purposes of approximately $637.9 million and $455.4 million, respectively. At December 31, 2020, the Company had net operating loss carryforwards for federal and state tax purposes of approximately $551.0 million and $388.5 million, respectively. Federal losses of $414.7 million begin to expire in 2023 and $223.2 million of the federal losses carry forward indefinitely. State losses of $409.2 million begin to expire in 2022 and $46.2 million of the state losses carry forward indefinitely. In addition, the Company has tax credit carryforwards for federal tax purposes of approximately $23.3 million as of December 31, 2021, which begin to expire in 2022. The Company also has capital loss carryforwards for federal tax purposes of $1.9 million, which begin to expire in 2022. The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership.

Management has recorded a valuation allowance for all of the deferred tax assets due to the uncertainty of future taxable income.

The Company incorporated a subsidiary in the United Kingdom in 2014. However, the subsidiary had zero activity in 2021 and as such, has no undistributed earnings. The Company dissolved the United Kingdom subsidiary in 2021.

The Company incorporated a subsidiary in Ireland during 2018. However, the subsidiary had no activity during 2019, 2020 and 2021, and as such, has no undistributed earnings.

The Company acquired Oncoceutics in 2021 and is including the activity for 2021 in its consolidated financial statements.

In general, if the Company experiences a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period (a Section 382 ownership change), utilization of its pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (and similar state laws). The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the net operating loss carryforwards before utilization and may be substantial. The ability of the Company to use its net operating loss carryforwards may be limited or lost if the Company experiences a Section 382 ownership change in connection with offerings or as a result of future changes in its stock ownership. Losses from a specific period may be subject to multiple limitations and would generally be limited by the lowest of those limitations.

The Company has determined that a Section 382 ownership change occurred in 2007, and as such, losses incurred prior to that date are subject to an annual limitation of at least $762,000. The Company evaluated Section 382 ownership changes subsequent to 2007 through September 30, 2020 and concluded that a Section 382 ownership change occurred in 2013 as a result of the initial public offering. As such, losses incurred prior to that date are subject to an annual limitation of at least $6.7 million. The acquired Oncoceutics net operating losses may be subject to limitations under Section 382, however no study has been completed as of the year ended December 31, 2021.

The Company has determined that there may be a future limitation on the Company's ability to utilize its entire federal R&D credit carryover. Therefore, the Company recognized an uncertain tax benefit associated with the federal R&D credit carryover during the years ended December 31, 2021 and 2020, as follows (in thousands):

Balance at December 31, 2019	$	4,023
Increases related to 2020		272
Increases related to prior periods		—
Balance at December 31, 2020		4,295
Increases related to 2021		391
Increases related to prior periods		48
Balance at December 31, 2021	$	4,734

On November 18, 2021, Governor Roy Cooper signed into law the 2021 Appropriations Act which phases out the corporate income tax for North Carolina. The Bill phases out the current 2.5% North Carolina corporate income tax rate over five years starting in 2025, reaching zero by 2030. For tax years beginning on or after January 1, 2025 the rate is 2.25%. The rate decreases to 2% in 2026 and 2027; and to 1% in 2028 and 2029. After 2029, the rate decreases to 0%. As a result of the revised tax rate, the Company adjusted its North Carolina net operating loss deferred tax asset as of December 31, 2021 by applying the revised tax rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately $7.1 million.

The Company has determined that it had no other material uncertain tax benefits for the year ended December 31, 2021. As of December 31, 2021, due to the carry forward of unutilized net operating losses and research and development credits, the Company is subject to U.S. federal and state income tax examinations for the tax years 2002 through 2021. The Company recognizes accrued interest related to unrecognized tax benefits in interest expense and penalties in operating expense. No amounts were accrued for the payment of interest and penalties at December 31, 2021.

The Tax Act subjects a US shareholder to tax on global intangible low-taxed income (GILTI) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognized deferred taxes for temporary basis differences expected to

reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred. The Company does not have a GILTI inclusion in 2019, 2020 or 2021; therefore, no GILTI tax has been recorded for the years ended December 31, 2020 and 2021.

Note 7. Significant Agreements

Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, the Company entered into a contract with BARDA for the advanced development of TEMBEXA as a medical countermeasure in the event of a smallpox release. Under the contract, BARDA agreed to reimburse the Company, plus pay a fixed fee, for the research and development of TEMBEXA as a broad-spectrum therapeutic antiviral for the treatment of smallpox infections. The contract consists of an initial performance period, referred to as the base performance segment, plus up to four extension periods, referred to as option segments, of which all have been exercised. Under the contract, the Company received $72.5 million in expense reimbursement and $4.6 million in fees.

The fourth option segment ended on September 1, 2021 and the contract has expired in accordance with its terms. For the years ended December 31, 2021, 2020, and 2019, the Company recognized revenue under this contract of $1.6 million, $5.3 million and $7.6 million, respectively.

License and Development Agreement with Cantex Pharmaceuticals, Inc.

On July 26, 2019, the Company entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which the Company acquired exclusive worldwide rights to develop and commercialize, for any and all uses, a glycosaminoglycan compound known as DSTAT, which is currently being studied for the treatment of acute myeloid leukemia. Under the terms of the license agreement, the Company is responsible for, and bears the future costs of, worldwide development and commercialization of DSTAT. In connection with the transaction, Cantex assigned to the Company all of its rights under its DSTAT supply agreements, including its bulk API agreement with Scientific Protein Laboratories LLC (SPL), pursuant to which SPL will exclusively produce DSTAT for the Company through October 2040.

In consideration for the license rights, the Company made an upfront cash payment of $30.0 million to Cantex and issued to Cantex 10.0 million shares of its common stock. For the twelve months ended December 31, 2019, the Company recognized $65.0 million of acquired in-process research and development expenses for the $30.0 million upfront cash payment, the fair value of the 10.0 million shares of common stock issued to Cantex and $0.1 million of transaction costs. The license agreement obligates the Company to pay Cantex regulatory milestone payments of up to $202.5 million upon receipt of product approvals in the United States, the European Union and Japan, and sales milestone payments of up to $385.0 million upon achievement of specified net sales levels. The Company also agreed to pay Cantex tiered royalties based on percentages of net sales beginning at 10% and not to exceed the high-teens.

SymBio Pharmaceuticals

On September 30, 2019, the Company entered into a license agreement with SymBio for the exclusive worldwide rights to develop, manufacture and commercialize BCV for all human indications, excluding the prevention and treatment of orthopoxviruses, including smallpox. Under the terms of the license agreement, SymBio will be responsible for, and bear the future costs of, worldwide development and commercialization of BCV in the licensed indications. Either party may terminate the license agreement upon the occurrence of a material breach by the other party (subject to standard cure periods), or upon certain events involving the bankruptcy or insolvency of the other party. SymBio may also terminate the license agreement without cause on a country-by-country basis upon ninety days prior notice.

In exchange for the license to SymBio under the Company's BCV rights, the Company received an upfront payment of $5.0 million in October 2019. In addition, the Company is eligible to receive up to $180.0 million in clinical, regulatory and commercial milestones worldwide, as well as low double-digit royalties based on net sales of BCV. Since entering into the license agreement in September 2019, the Company has recognized all of the $5.0 million of revenue related to the upfront payment.

Ohara Agreement

In 2019, Oncoceutics, Inc., a Delaware corporation (Oncoceutics) entered into a license, development and commercialization agreement with Ohara Pharmaceutical Co., Ltd. for ONC201 in Japan. The Company is entitled to receive up to $2.5 million in nonrefundable regulatory milestone payments. The Company is entitled to tiered royalties based on the aggregate annual net sales of all products, as defined in the agreement, in Japan.

CR Sanjiu Agreement

In December 2020, Oncoceutics entered into a license, development and commercialization agreement with China Resources Sanjiu Medical & Pharmaceutical Co., Ltd. (CR Sanjiu). Oncoceutics granted CR Sanjiu an exclusive royalty bearing license to develop and commercialize ONC201 in China, Hong Kong, Macau and Taiwan (CR Sanjiu Territory). The Company is entitled to receive up to $5.0 million in nonrefundable regulatory milestone payments. The Company is entitled to tiered royalties based on the aggregate annual net sales of all licensed products, as defined in the agreement, in China.

Note 8. Oncoceutics Acquisition

On January 7, 2021, the Company, Ocean Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (Merger Sub), Oncoceutics and Fortis Advisors, LLC solely in its capacity as representative of the securityholders of Oncoceutics (the Securityholders' Representative), entered into an Agreement and Plan of Merger (the Merger Agreement). Concurrently with the execution of the Merger Agreement, Merger Sub merged with and into Oncoceutics (the Merger) whereupon the separate corporate existence of Merger Sub ceased, with Oncoceutics continuing as the surviving corporation of the Merger as a wholly-owned subsidiary of the Company.

As consideration for the Merger, the Company (a) paid an upfront cash payment of approximately $25.0 million, subject to certain customary adjustments, (b) issued an aggregate of 8,723,769 shares of the Company's common stock, (c) issued a promissory note to the Securityholders' Representative in the principal amount of $14.0 million (the Seller Note), to be paid in cash, subject to the terms and conditions of the Merger Agreement and the Seller Note, upon the one year anniversary of the closing of the Merger, and (d) agreed to make contingent payments up to an aggregate of $360.0 million based on the achievement of certain development, regulatory and commercialization events as set forth in the Merger Agreement, as well as additional tiered royalty payments based upon future net sales of ONC 201 and ONC 206 products, subject to certain reductions as set forth in the Merger Agreement, and a contingent payment in the event the Company receives any proceeds from the sale of a rare pediatric disease priority review voucher based on Oncoceutics' products. The closing payment may be adjusted after the closing, pursuant to procedures set forth in the Merger Agreement, in connection with the finalization of the cash, transaction expenses, debt and working capital amounts at closing. As of December 31, 2021, the Company has recorded an estimated liability of $0.2 million related to closing payment adjustments. Additionally, as of December 31, 2021, the Company has recorded an estimated receivable of $0.6 million related to the repayment of certain severance amounts due from the Oncoceutics' shareholders. The promissory note totaling $14.0 million and the net of the previously mentioned receivable and liability, less $0.4 million held back as a reserve against estimated post-closing transaction expenses, was paid to the Oncoceutics' shareholders in January 2022. A $20.0 million milestone payment was paid and expensed to research and development expenses in the fourth quarter of 2021 related to the achievement of the 20% ORR, evaluated by BICR, of ONC201 in recurrent H3 K27M-mutant glioma patients success milestone.

The Company accounted for the Oncoceutics acquisition as an asset acquisition as the majority of the value of the assets acquired related to the ONC201 acquired in-process research and development (IPR&D) asset. In accordance with Accounting Standards Codification (ASC) Subtopic 730-10-25, Accounting for Research and Development Costs, the up-front payments to acquire a new drug compound, are immediately expensed as acquired IPR&D and future milestone payments are expensed to research and development expenses when paid or payable in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Therefore, the portion of the purchase price that was allocated to the IPR&D assets acquired was immediately expensed. Other assets acquired and liabilities assumed, were recorded at fair value.

The following represents the consideration paid and purchase price allocation for the acquisition of Oncoceutics (in thousands, except for per share data):

Cash	$	23,836
One-year closing anniversary payment		14,000
Shares common stock issued as consideration		8,723,769
Stock price per share on effective date		4.98
Value of estimated common stock consideration		43,445
Total consideration	**$**	**81,281**
Net assets acquired	$	(1,310)
IPR&D assets expensed		82,591
Total purchase price allocated	**$**	**81,281**
Transaction costs expensed to IPR&D[(1)]	$	299
Total IPR&D expensed	**$**	**82,890**

(1) As a result of the asset acquisition accounting, the transaction costs associated with the acquisition should be included in the costs of the assets acquired. The primary asset acquired, the IPR&D asset, was expensed and the transaction related costs were included with and expensed with this asset. The transaction costs primarily included financial advisor fees, legal expenses and auditor expenses. Additionally, there were $0.6 million of expenses related to this acquisition recorded in the fourth quarter of 2020 to general and administrative expenses in the Consolidated Statements of Operations and Comprehensive Loss.

Note 9. Restructuring Costs

In May 2019, the Company made the decision to discontinue the development of oral and IV BCV development programs for the treatment of Adenovirus (AdV) in stem-cell transplant (HCT) patients. The Company's development efforts with respect to BCV are now focused on the treatment of smallpox. As a result, the Company restructured its operations, which included a reduction in workforce of 43 full-time employees and the accrual of expenses to close-out the clinical trials for the oral and IV development programs of BCV in AdV (study 210, study 211, AdAPT) and other supportive BCV development programs. The Company recorded charges for one-time employee termination benefits of $3.3 million, contract close-out costs of $2.0 million, other BCV development costs of $0.3 million, and losses on disposals of fixed assets of $0.3 million during the twelve months ended December 31, 2019. The $2.0 million of contract close-out costs were recorded through an increase in liabilities of $1.5 million with the remainder recognized through the expensing of prepaid balances. As of December 31, 2019, the Company had a clinical trial accrual balance related to the AdAPT, 210 and 211 trial terminations of $27,000 and other development costs accrual balance of $0.1 million. As of December 31, 2019, the Company had a severance accrual balance of $0.2 million.

The following table summarizes the restructuring charges (in thousands) recorded for the twelve months ended December 31, 2019:

	Employee Termination Benefits	Clinical Trial Close-out Costs	Other Development Costs	Fixed Asset Disposals	Total
Research and development	$ 1,437	$ 2,021	$ 339	$ —	$ 3,797
General and administrative	1,909	—	—	—	1,909
Interest income and other, net	—	—	—	250	250
Total restructuring expenses	$ 3,346	$ 2,021	$ 339	$ 250	$ 5,956

The following table sets forth the accrual activity for employee termination benefits and contract close-out costs (in thousands) for the twelve months ended December 31, 2019. No additional charges are expected to be incurred.

	Employee Termination Benefits	Clinical Trial Close-out Costs	Other Development Costs	Fixed Asset Disposals	Total
Balance at January 1, 2019	$ —	$ —	$ —	$ —	$ —
Accruals	3,335	2,131	315	—	5,781
Revised estimates	11	(621)	24	250	(336)
Payments	(3,163)	(1,483)	(229)	(250)	(5,125)
Balance at December 31, 2019	$ 183	$ 27	$ 110	$ —	$ 320

The following table sets forth the accrual activity for employee termination benefits and contract close-out costs (in thousands) for the twelve months ended December 31, 2020.

	Employee Termination Benefits	Clinical Trial Close-out Costs	Other Development Costs	Total
Balance at December 31, 2019	$ 183	$ 27	$ 110	$ 320
Revised estimates	—	(23)	(10)	(33)
Payments	(183)	(4)	(100)	(287)
Balance at December 31, 2020	$ —	$ —	$ —	$ —

For the twelve months ended December 31, 2020, the revised accrual estimates resulted in a decrease to research and development expenses of $33,000. Additionally, during the twelve ended December 31, 2020, refunds of unused deposits of $1.3 million were received, which were previously recorded in prepaid expenses and other current assets on the Consolidated Balance Sheet.

Note 10. Selected Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for 2021 and 2020 are as follows (in thousands, except share and per share data):

	2021 Quarters			
	Fourth	Third	Second	First
Revenue	$ 46	$ 107	$ 391	$ 1,435
Operating loss	(39,532)	(18,600)	(17,815)	(97,453)
Net loss	(39,498)	(18,560)	(17,763)	(97,415)
Net loss per share, basic and diluted	$ (0.45)	$ (0.21)	$ (0.21)	$ (1.21)
Weighted-average shares outstanding, basic and diluted	86,867,070	86,335,357	86,225,836	80,204,094

	2020 Quarters			
	Fourth	Third	Second	First
Revenue	$ 1,120	$ 1,609	$ 1,402	$ 1,241
Operating loss	(11,757)	(11,560)	(10,286)	(10,913)
Net loss	(11,675)	(11,411)	(10,016)	(10,420)
Net loss per share, basic and diluted	$ (0.19)	$ (0.18)	$ (0.16)	$ (0.17)
Weighted-average shares outstanding, basic and diluted	62,702,181	62,242,456	62,042,778	61,742,035

Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per share calculations will not necessarily equal the annual per share calculation. Diluted weighted-average shares outstanding are

identical to basic weighted-average shares outstanding and diluted net loss per share is identical to basic net loss per share for all quarters of 2021 and 2020.

Note 11. Subsequent Events

The Company has evaluated subsequent events through the issuance date of these financial statements to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2021, and events which occurred subsequently but were not recognized in the financial statements.

On January 31, 2022 (the Effective Date), the Company entered into a Loan and Security Agreement (the Loan Agreement), by and between the Company, as borrower, and Silicon Valley Bank, as the lender (the Lender). The Loan Agreement provides for a four-year secured revolving loan facility (the Credit Facility) in an aggregate principal amount of up to $50.0 million. Proceeds from the Credit Facility may be used for working capital and general corporate purposes. The Company has no obligation to draw down any amount under the Credit Facility, and has not drawn down any amount as of the date of this filing.

The Company may borrow, repay and re-borrow funds under the Credit Facility without a prepayment penalty until January 31, 2026 (the Maturity Date), at which time the Credit Facility expires, and all outstanding revolving loans under the Credit Facility, together with all accrued and unpaid interest, must be repaid. No exit fee exists upon expiration of the Credit Facility on the Maturity Date. Subject to the satisfaction of certain liquidity ratios, the full $50.0 million of the Credit Facility will be available for the Company to borrow on a non-formula basis. If the Company is unable to meet these liquidity ratios, then availability under the Credit Facility is determined based on a borrowing base equal to percentages of certain accounts receivable and certain purchase orders (which include prospective options for BARDA to procure TEMBEXA treatment courses) for the Company's goods in accordance with a formula set forth in the Loan Agreement.

Borrowings under the Credit Facility accrue interest at a floating per annum rate of the greater of (i) 1.50% above the Prime Rate (as defined below) and (ii) 4.75%. Prime Rate is defined as the rate of interest per annum published in The Wall Street Journal or any successor publication thereto as the "prime rate". If such rate of interest from The Wall Street Journal becomes unavailable, the "Prime Rate" shall mean the rate of interest per annum announced by the Lender as its prime rate in effect. In each case, in the event such prime rate is less than zero, such rate shall be deemed to be zero for purposes of the Loan Agreement. The Company must also pay an unused line fee equal to 0.25% per annum on the unused portion of the Credit Facility, payable quarterly in arrears. Upon the termination of the Loan Agreement for any reason prior to the Maturity Date, the Company will be required to pay to the Lender an early termination fee of $0.5 million. The Loan Agreement also requires the Company to pay the Lender a non-refundable commitment fee of $0.5 million, payable in four equal installments beginning on the Effective Date and each anniversary of the Effective Date thereafter until January 31, 2025.

The Company's obligations under the Loan Agreement are secured by a first lien on substantially all assets of the Company other than the Company's intellectual property, with a negative pledge on the Company's intellectual property.

The Loan Agreement contains customary affirmative and negative covenants and customary events of default that permit the Lender to accelerate the Company's outstanding obligations under the Loan Agreement, all as set forth in the Loan Agreement. The Loan Agreement also contains financial covenants requiring the Company to maintain specified liquidity and cash levels at certain times as set forth in the Loan Agreement.

ITEM. 9 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of December 31, 2021, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports 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 is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control system was designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Our internal control over financial reporting includes those policies and procedures that:

i. pertain to the maintenance of records, that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
ii. provide reasonable assurance that transactions are recorded as necessary to permit preparations of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
iii. provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. In making the assessment of internal controls over financial reporting, our management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework* (2013 framework). Based on that assessment and those criteria, management has concluded that our internal control over financial reporting was effective as of December 31, 2021.

Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this Annual Report, has issued an attestation report on the Company's internal control over financial reporting, a copy of which appears in Item 8 of this Annual Report.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item and not set forth below will be set forth in the section headed “Election of Directors” and “Executive Officers” in our Proxy Statement for our 2022 Annual Meeting of Stockholders (Proxy Statement), to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021, and is incorporated herein by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://www.chimerix.com* under the Corporate Governance section of our Investor Relations page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in the section headed “Executive Compensation” in our Proxy Statement 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 will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth in the section headed “Transactions With Related Persons” in our Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be set forth in the section headed “Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. *Financial Statements.* The financial statements and reports of independent registered public accounting firm are filed as part of this Annual Report (see "Index to Consolidated Financial Statements" at Item 8).

2. *Financial Statement Schedules.* No financial statement schedules are included because the information is either provided in the consolidated financial statements, is not required under the instructions or is immaterial, and such schedules, therefore have been omitted.

3. *Exhibits.* The following exhibits have been or are being filed herewith and are numbered in accordance with Item 601 of Regulation S-K:

EXHIBIT INDEX

Exhibit Number	Description of Document
2.1** (33)	Agreement and Plan of Merger, dated January 7, 2021, by and among the Registrant, Oncoceutics, Merger Sub
3.1 (1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2 (1)	Amended and Restated Bylaws of the Registrant.
4.1 (1)	Form of Common Stock Certificate of the Registrant.
4.2	Description of Common Stock
10.1+ (1)	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+ (1)	Chimerix, Inc. 2002 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Form of Stock Option Grant Notice thereunder.
10.3+ (1)	Chimerix, Inc. 2012 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Form of Stock Option Grant Notice and Form of Restricted Stock Unit Award Agreement and Form of Restricted Stock Unit Award Grant Notice thereunder.
10.4+(15)	Form of Stock Option Agreement, Notice of Exercise and Form of Stock Option Grant Notice and Form of Restricted Stock Unit Award Agreement and Form of Restricted Stock Unit Award Grant Notice under Chimerix, Inc. 2013 Equity Incentive Plan.
10.5+ (2)	Chimerix, Inc. 2013 Equity Incentive Plan, as amended.
10.6+ (26)	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise for Inducement Grant Outside of 2013 Equity Incentive Plan
10.7+ (1)	Chimerix, Inc. 2013 Employee Stock Purchase Plan.
10.8+ (28)	Chimerix, Inc. Non-Employee Director Compensation Policy.
10.9+ (23)	Chimerix, Inc. Officer Severance Benefit Plan, as amended.
10.10+ (10)	Directorship Offer Letter to Catherine L. Gilliss dated June 13, 2014.
10.11+ (10)	Directorship Offer Letter to Patrick Machado dated May 30, 2014.
10.12 (1)	Office Lease by and between the Registrant and ACP 2505 Meridian LLC dated September 1, 2007, as amended.
10.13 (4)	Fifth Amendment to Office Lease dated July 2, 2014 by and between the Registrant and AREP Meridian I LLC.
10.14 (8)	Sixth Amendment to Office Lease dated April 28, 2015 by and between the Registrant and IVC Meridian TT O, LLC.
10.15 (15)	Seventh Amendment to Office Lease dated March 10, 2017 by and between the Registrant and IVC Meridian TT O, LLC.
10.16 (16)	Eighth Amendment to Office Lease dated July 13, 2017 by and between the Registrant and IVC Meridian TT O, LLC.
10.17 (29)	Ninth Amendment to Office Lease, dated June 24, 2020, by and between the Registrant and BRI 1875 Meridian, LLC.
10.18 (5)	Lease Agreement by and between the Registrant and Northwood RTC LLC dated March 10, 2014.

10.19 [19]	First Amendment to Industrial Building Lease dated December 14, 2017 by and between Registrant and CLPF - Research Center, LLC.
10.20** [29]	Second Amendment to Lease Agreement, dated July 30, 2020, by and between the Registrant and CLPF-Research Center, LLC.
10.21* [1]	Contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.22* [6]	Contract modification No. 14, dated May 30, 2013, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.23* [7]	Contract modification No. 15, dated August 28, 2013, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.24* [7]	Contract modification No. 16, dated December 10, 2013, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.25 [3]	Contract modification No. 17, dated April 14, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.26 [10]	Contract modification No. 18, dated May 6, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.27* [4]	Contract modification No. 19, dated August 27, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.28 [4]	Contract modification No. 20, dated October 27, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.29* [10]	Contract modification No. 21, dated November 7, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.30 [10]	Contract modification No. 22, dated December 11, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.31 [10]	Contract modification No. 23, dated December 22, 2014, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.32 [10]	Contract modification No. 24, dated February 19, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.33 [8]	Contract modification No. 25, dated March 26, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.34 [9]	Contract modification No. 26, dated June 18, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.35 [9]	Contract modification No. 27, dated July 14, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.36* [30]	Contract modification No. 28, dated September 1, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.37* [30]	Contract modification No. 29, dated September 11, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.

10.38* [11]	Contract modification No. 30, dated November 12, 2015, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.39* [12]	Contract modification No. 31, dated April 8, 2016, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.40* [12]	Contract modification No. 32, dated May 5, 2016, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.41* [13]	Contract modification No. 33, dated June 17, 2016, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.42* [14]	Contract modification No. 34, dated August 3, 2016, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.43 [15]	Contract modification No. 35, dated October 21, 2016, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.44 [15]	Contract modification No. 36, dated January 23, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.45 [16]	Contract modification No. 37, dated March 27, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.46 [17]	Contract modification No. 38, dated April 3, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.47 [17]	Contract modification No. 39, dated May 11, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.48 [17]	Contract modification No. 40, dated June 16, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.49 [18]	Contract modification No. 41, dated July 24, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.50 [18]	Contract modification No. 42, dated August 25, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.51 [18]	Contract modification No. 43, dated September 22, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.52 [18]	Contract modification No. 44, dated September 28, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.53 [19]	Contract modification No. 45, dated October 20, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.54 [19]	Contract modification No. 46, dated November 27, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.55* [19]	Contract modification No. 47, dated December 21, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.

10.56 [19]	Contract modification No. 48, dated December 21, 2017, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.57* [19]	Contract modification No. 49, dated February 27, 2018, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.58* [20]	Contract modification No. 50, dated March 20, 2018, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.59* [21]	Contract modification No. 51, dated May 31, 2018, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.60* [21]	Contract modification No. 52, dated July 11, 2018, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.61 [22]	Contract modification No. 53, dated September 6, 2018, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.62 [23]	Contract modification No. 54, dated December 3, 2018, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.63* [23]	Contract modification No. 55, dated January 10, 2019, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.64 [25]	Contract modification No. 56, dated March 5, 2019, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.65** [26]	Contract modification No. 57, dated July 12, 2019, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.66** [28]	Contract modification No. 58, dated December 13, 2019, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.67 [29]	Contract modification No. 59, dated May 11, 2020, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.68** [29]	Contract modification No. 60, dated June 17, 2020, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.69** [29]	Contract modification No. 61, dated July 28, 2020, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.70 [30]	Contract modification No. 62, dated September 11, 2020, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.71** [30]	Contract modification No. 63, dated September 28, 2020 to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.72 [33]	Contract modification No. 64, dated January 26, 2021 to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.73 [34]	Contract modification No. 65, dated April 16, 2021 to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.

10.74 [35]	Contract modification No. 66, dated May 24, 2021 to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.75** [35]	Contract modification No. 67, dated September 20, 2021 to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
10.76+ [24]	Employment Offer Letter to Michael Sherman dated April 2, 2019.
10.77+ [24]	Employment Offer Letter to Michael Andriole dated April 4, 2019.
10.78** [27]	License and Development Agreement, dated July 26, 2019, by and between the Registrant and Cantex Pharmaceuticals, Inc.
10.79** [27]	Supply Agreement, dated October 2, 2015, by and between the Registrant (as successor to Cantex Pharmaceuticals, Inc.) and Scientific Protein Laboratories LLC.
10.80** [31]	Amendment to the Supply Agreement, dated December 16, 2020, by and between Chimerix, Inc. and Scientific Protein Laboratories, LLC.
10.81** [27]	License Agreement, dated September 30, 2019, by and between the Registrant and SymBio Pharmaceuticals Limited.
10.82 [32]	Promissory Noted, dated January 7, 2021, by and between the Registrant and Fortis Advisors, LLC, solely in its capacity as Securityholders' Representative.
10.83** #	Loan and Security Agreement, dated January 31, 2022, by and between the Registrant and Silicon Valley Bank.
21.1	Subsidiaries of Chimerix, Inc.
23.1	Consent of Ernst & Young LLP, an Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

+	Indicates management contract or compensatory plan.
#	Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.
*	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
**	Certain confidential information contained in this exhibit, marked by brackets, has been omitted pursuant to Item 601 of Regulation S-K because the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.
(1)	Incorporated by reference to Chimerix, Inc.'s Registration Statement on Form S-1 (No. 333-187145), as amended.
(2)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on June 23, 2014.
(3)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 9, 2014.
(4)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 7, 2014.
(5)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on March 14, 2014.
(6)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 14, 2013.
(7)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 7, 2014.
(8)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 11, 2015.
(9)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 6, 2015.
(10)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 6, 2015.
(11)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on February 29, 2016
(12)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 9, 2016.
(13)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 8, 2016.
(14)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 7, 2016.
(15)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 2, 2017.
(16)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 9, 2017.
(17)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 7, 2017.
(18)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on October 11, 2017.
(19)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 1, 2018.
(20)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 7, 2018.
(21)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 8, 2018.
(22)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 8, 2018.
(23)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 5, 2019.
(24)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on April 10, 2019.

(25)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 9, 2019.
(26)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 8, 2019.
(27)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 5, 2019.
(28)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on February 25, 2020.
(29)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 10, 2020.
(30)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 11, 2020.
(31)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on December 23, 2020.
(32)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on January 13, 2021.
(33)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on February 25, 2021.
(34)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 6, 2021.
(35)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 4, 2021.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Chimerix, Inc.

Date: March 1, 2022 By: /s/ Michael A. Sherman

Michael A. Sherman
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael A. Sherman and Michael T. Andriole, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael A. Sherman Michael A. Sherman	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2022
/s/ Michael T. Andriole Michael T. Andriole	Chief Business and Financial Officer (Principal Financial Officer)	March 1, 2022
/s/ David Jakeman David Jakeman	Executive Director of Finance and Accounting (Principal Accounting Officer)	March 1, 2022
/s/ Martha J. Demski Martha J. Demski	Chair of the Board of Directors	March 1, 2022
/s/ Catherine L. Gilliss Catherine L. Gilliss, PhD, RN, FAAN	Member of the Board of Directors	March 1, 2022
/s/ Patrick Machado Patrick Machado	Member of the Board of Directors	March 1, 2022
/s/ Robert J. Meyer Robert J. Meyer, MD	Member of the Board of Directors	March 1, 2022
/s/ Fred A. Middleton Fred A. Middleton	Member of the Board of Directors	March 1, 2022
/s/ Pratik S. Multani Pratik S. Multani, MD	Member of the Board of Directors	March 1, 2022
/s/ Victoria Vakiener Victoria Vakiener	Member of the Board of Directors	March 1, 2022

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (this "Agreement") is dated as of the Effective Date between **SILICON VALLEY BANK**, a California corporation ("**Bank**"), and the borrower listed on Schedule I hereto ("**Borrower**"). The parties agree as follows:

1. LOAN AND TERMS OF PAYMENT

1.1 Revolving Line.

(a) Availability. Subject to the terms and conditions of this Agreement, and to deduction of Reserves, Bank shall make Advances not exceeding the Availability Amount. Amounts borrowed under the Revolving Line may be prepaid or repaid as set forth on Schedule I hereto.

(b) Termination; Repayment. The Revolving Line terminates on the Revolving Line Maturity Date, when the outstanding principal amount of all Advances, the accrued and unpaid interest thereon, and all other outstanding Obligations relating to the Revolving Line shall be immediately due and payable.

1.2 Reserved.

1.3 Reserved.

1.4 Reserved.

1.5 Reserved.

1.6 Reserved.

1.7 Overadvances. If, at any time when a Streamline Period is not in effect, the sum of (a) the aggregate outstanding principal amount of any Advances, exceeds the lesser of (i) the Revolving Line or (ii) the Borrowing Base, Borrower shall immediately pay to Bank in cash the amount of such excess (such excess, the "**Overadvance**"). Without limiting Borrower's obligation to repay Bank any Overadvance, Borrower shall pay Bank interest on the outstanding amount of any Overadvance, on demand, at a rate per annum equal to the rate that is otherwise applicable to Advances plus [*].

1.8 Payment of Interest on the Credit Extensions.

(a) Interest Payments.

(i) Advances. Interest on the principal amount of each Advance is payable as set forth on Schedule I hereto.

(b) Interest Rate.

(i) Advances. Subject to Section 1.8(c), the outstanding principal amount of any Advance shall accrue interest as set forth on Schedule I hereto.

(ii) All-In Rate. Notwithstanding any terms in this Agreement to the contrary, if at any time the interest rate applicable to any Obligations is less than zero percent (0.0%), such interest rate shall be deemed to be zero percent (0.0%) for all purposes of this Agreement.

(c) Default Rate. Immediately, upon the occurrence and during the continuance of an Event of Default, the outstanding Obligations shall bear interest at a rate per annum which is [*] above the rate that is otherwise applicable thereto (the "**Default Rate**"). Fees and expenses which are required to be paid by Borrower pursuant to the Loan Documents (including, without limitation, Bank Expenses) but are not paid when due shall bear interest until paid at a rate equal to the highest rate applicable to the Obligations. Payment or acceptance of the increased interest rate provided in this Section 1.8(c) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Bank.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) Adjustment to Interest Rate. Each change in the interest rate applicable to any amounts payable under the Loan Documents based on changes to the Prime Rate shall be effective on the effective date of any change to the Prime Rate and to the extent of such change.

(e) Interest Computation. Interest shall be computed as set forth on Schedule I hereto. In computing interest, the date of the making of any Credit Extension shall be included and the date of payment shall be excluded; provided, however, that if any Credit Extension is repaid on the same day on which it is made, such day shall be included in computing interest on such Credit Extension.

1.9 Fees. Borrower shall pay to Bank:

(a) Revolving Line Commitment Fee. A fully earned, non-refundable commitment fee as set forth on Schedule I hereto;

(b) Good Faith Deposit. On or prior to the Effective Date, a good faith deposit in an amount equal to [*]; provided that any portion of such good faith deposit in excess of any Bank Expenses incurred through the Effective Date shall be refunded to Borrower promptly thereafter.

(c) Termination Fee. Upon termination of this Agreement or the termination of the Revolving Line for any reason prior to the Revolving Line Maturity Date, in addition to the payment of any other amounts then-owing, a termination fee in an amount equal to Five Hundred Thousand Dollars ($500,000) which shall be fully earned and non-refundable as of such date;

(d) Unused Revolving Line Facility Fee. Payable quarterly in arrears on the last calendar day of the calendar quarter occurring thereafter prior to the Revolving Line Maturity Date, and on the Revolving Line Maturity Date, a fee (the "**Unused Revolving Line Facility Fee**") in an amount equal to one quarter of one percent (.25%) per annum of the average unused portion of the Revolving Line, as determined by Bank, computed on the basis of a year with the applicable number of days as set forth in Section 1.8(e), which shall be fully earned and non-refundable as of such date. The unused portion of the Revolving Line, for purposes of this calculation, shall be calculated on a calendar year basis and shall equal the difference between (i) the Revolving Line, and (ii) the average for the period of the daily closing balance of the Revolving Line outstanding.

(e) Bank Expenses. All Bank Expenses incurred through and after the Effective Date, when due (or, if no stated due date, upon demand by Bank).

Unless otherwise provided in this Agreement or in a separate writing by Bank, Borrower shall not be entitled to any credit, rebate, or repayment of any fees earned by Bank pursuant to this Agreement notwithstanding any termination of this Agreement or the suspension or termination of Bank's obligation to make loans and advances hereunder. Bank may deduct amounts owing by Borrower under the clauses of this Section 1.9 pursuant to the terms of Section 1.10(c). Bank shall provide Borrower written notice of deductions made pursuant to the terms of the clauses of this Section 1.9.

1.10 Payments; Application of Payments; Debit of Accounts.

(a) All payments (including prepayments) to be made by Borrower under any Loan Document shall be made in immediately available funds in Dollars, without setoff, counterclaim, or deduction, before 12:00 p.m. Eastern time on the date when due. Payments of principal and/or interest received after 12:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment shall be due the next Business Day, and additional fees or interest, as applicable, shall continue to accrue until paid.

(b) Bank has the exclusive right to determine the order and manner in which all payments with respect to the Obligations may be applied. Borrower shall have no right to specify the order or the accounts to which Bank shall allocate or apply any payments required to be made by Borrower to Bank or otherwise received by Bank under this Agreement when any such allocation or application is not specified elsewhere in this Agreement.

(c) Bank may debit any of Borrower's deposit accounts maintained with Bank, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Bank when due under the Loan Documents. These debits shall not constitute a set-off.

1.11 Change in Circumstances.

(a) Increased Costs. If any Change in Law shall: (i) impose, modify or deem applicable any reserve, special deposit, compulsory loan, insurance charge or similar requirement against assets of, deposits with or for the account of, or advances, loans or other credit extended or participated in by, Bank, (ii) subject Bank to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (b) through (d) of the definition of Excluded Taxes, and (C) Connection Income Taxes) on its loans, loan principal, letters of credit, commitment, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, or (iii) impose on Bank any other condition, cost or expense (other than Taxes) affecting this Agreement or Credit Extensions made by Bank, and the result of any of the foregoing shall be to increase the cost to Bank of making, converting to, continuing or maintaining any Credit Extension (or of maintaining its obligation to make any such Credit Extension), or to reduce the amount of any sum received or receivable by Bank hereunder (whether of principal, interest or any other amount) then, upon written request of Bank, Borrower shall promptly pay to Bank such additional amount or amounts as will compensate Bank for such additional costs incurred or reduction suffered.

(b) Capital Requirements. If Bank determines that any Change in Law affecting Bank regarding capital or liquidity requirements, has or would have the effect of reducing the rate of return on Bank's capital as a consequence of this Agreement, the Revolving Line or the Credit Extensions made by Bank to a level below that which Bank could have achieved but for such Change in Law (taking into consideration Bank's policies with respect to capital adequacy and liquidity), then from time to time upon written request of Bank, Borrower shall promptly pay to Bank such additional amount or amounts as will compensate Bank for any such reduction suffered.

(c) Delay in Requests. Failure or delay on the part of Bank to demand compensation pursuant to this Section 1.11 shall not constitute a waiver of Bank's right to demand such compensation; provided that Borrower shall not be required to compensate Bank pursuant to subsection (a) for any increased costs incurred or reductions suffered more than nine (9) months prior to the date that Bank notifies Borrower of the Change in Law giving rise to such increased costs or reductions (except that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the nine (9) month period shall be extended to include the period of retroactive effect).

1.12 Taxes.

(a) Payments Free of Taxes. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by Applicable Law. If any Applicable Law (as determined in the good faith discretion of Borrower) requires the deduction or withholding of any Tax from any such payment by Borrower, then (i) Borrower shall be entitled to make such deduction or withholding, (ii) Borrower shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with Applicable Law, and (iii) if such Tax is an Indemnified Tax, the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 1.12) Bank receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) Payment of Other Taxes by Borrower. Without limiting the provisions of subsection (a) above, Borrower shall timely pay any Other Taxes to the relevant Governmental Authority in accordance with Applicable Law.

(c) Tax Indemnification. Without limiting the provisions of subsections (a) and (b) above, Borrower shall, and does hereby, indemnify Bank, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 1.12) payable or paid by Bank or required to be withheld or deducted from a payment to Bank and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by Bank shall be conclusive absent manifest error.

(d) Evidence of Payments. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to this Section 1.12, Borrower shall deliver to Bank a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Bank.

(e) Status of Bank. If Bank (including any assignee or successor) is entitled to an exemption from or reduction of withholding tax with respect to payments made under any Loan Document, it shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, Bank, if reasonably requested by Borrower, shall deliver such other

documentation prescribed by Applicable Law or reasonably requested by Borrower as will enable Borrower to determine whether or not Bank is subject to backup withholding or information reporting requirements. Without limiting the generality of the foregoing, Bank shall deliver whichever of IRS Form W-9, IRS Form W-8BEN-E, IRS Form W-8ECI or W-8IMY is applicable, as well as any applicable supporting documentation or certifications.

1.13 Procedures for Borrowing.

(a) Advances. Subject to the prior satisfaction of all other applicable conditions to the making of an Advance set forth in this Agreement (which must be satisfied no later than 12:00 p.m. Eastern time on the applicable Funding Date), to obtain an Advance, Borrower (via an individual duly authorized by an Administrator) shall notify Bank (which notice shall be irrevocable) by 12:00 p.m. Eastern time on the Funding Date of the Advance. Such notice shall be made through Bank's online banking program, provided, however, if Borrower is not utilizing Bank's online banking program, then such notice shall be in a written format acceptable to Bank that is executed by an Authorized Signer. In connection with any such notification, Borrower shall deliver to Bank by electronic mail or through Bank's online banking program such reports and information, including without limitation, sales journals, cash receipts journals, accounts receivable aging reports, as Bank may reasonably request. Bank shall have received satisfactory evidence that the Board has approved that such Authorized Signer may provide such notices and request Advances (which requirement may be deemed satisfied by the prior delivery of Borrowing Resolutions or a secretary's certificate that certifies as to such Board approval).

(b) Bank shall credit proceeds of a Credit Extension to the Designated Deposit Account. Bank may make Advances under this Agreement based on instructions from an Authorized Signer or without instructions if such Advances are necessary to meet Obligations which have become due.

2. CONDITIONS OF CREDIT EXTENSIONS

2.1 Conditions Precedent to Initial Credit Extension. Bank's obligation to make the initial Credit Extension is subject to the condition precedent that Bank shall have received, in form and substance satisfactory to Bank, such documents, and completion of such other matters, as Bank may reasonably deem necessary or appropriate, including, without limitation:

(a) duly executed Loan Documents;

(b) duly executed Control Agreements with UBS;

(c) the Operating Documents of Borrower and long-form good standing certificates of Borrower certified by the Secretary of State of the State of Delaware and the Secretary of State (or equivalent agency) of each other jurisdiction in which Borrower is qualified to conduct business, in each case as of a date no earlier than thirty (30) days prior to the Effective Date;

(d) certificate duly executed by a Responsible Officer or secretary of Borrower with respect to Borrower (i) Operating Documents and (ii) Borrowing Resolutions;

(e) certified copies, dated as of a recent date, of searches for financing statement filed in the central filing office of the State of Delaware, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(f) duly executed Perfection Certificate of Borrower;

(g) Intellectual Property search results;

(h) with respect to the initial Advance, a completed Borrowing Base Statement (and any schedules related thereto and including any other information requested by Bank with respect to Borrower's Accounts); and

(i) payment of the fees and Bank Expenses then due as specified in Section 1.9 hereof.

2.2 Conditions Precedent to all Credit Extensions. Bank's obligation to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt of Borrower's Credit Extension request and the related materials and documents as required by and in accordance with Section 1.13;

(b) the representations and warranties in this Agreement shall be true and correct in all material respects as of the date of any Credit Extension request and as of the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date, and no Default or Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in this Agreement remain true and correct in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date; and

(c) a Material Adverse Change shall not have occurred and be continuing.

2.3 Covenant to Deliver. Borrower shall deliver to Bank each item required to be delivered to Bank under this Agreement as a condition precedent to any Credit Extension. A Credit Extension made prior to the receipt by Bank of any such item shall not constitute a waiver by Bank of Borrower's obligation to deliver such item, and the making of any Credit Extension in the absence of a required item shall be in Bank's sole discretion.

3. CREATION OF SECURITY INTEREST

3.1 Grant of Security Interest.

(a) Borrower hereby grants Bank, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Bank, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof.

(b) Borrower acknowledges that it previously has entered, or may in the future enter, into Bank Services Agreements with Bank. Regardless of the terms of any Bank Services Agreement, Borrower agrees that any amounts Borrower owes Bank thereunder shall be deemed to be Obligations hereunder and that it is the intent of Borrower and Bank to have all such Obligations secured by the first priority perfected security interest in the Collateral granted herein (subject to Permitted Liens).

3.2 Authorization to File Financing Statements. Borrower hereby authorizes Bank to file financing statements, without notice to Borrower, with all jurisdictions deemed necessary or appropriate by Bank to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral, by either Borrower or any other Person, shall be deemed to violate the rights of Bank under the Code. Such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect.

3.3 Termination. If this Agreement is terminated, Bank's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as Bank's obligation to make Credit Extensions has terminated, Bank shall, at Borrower's sole cost and expense, terminate its security interest and release its Liens in the Collateral and all rights therein shall revert to Borrower. In the event (a) all Obligations (other than inchoate indemnity obligations), except for Bank Services, are satisfied in full, and (b) this Agreement is terminated, Bank shall terminate the security interest granted herein upon Borrower providing cash collateral acceptable to Bank in its good faith business judgment for Bank Services, if any. In the event such Bank Services consist of outstanding Letters of Credit, Borrower shall provide to Bank cash collateral in an amount equal to at least (i) one hundred five percent (105.0%) of the face amount of all such Letters of Credit denominated in Dollars and (ii) one hundred ten percent (110.0%) of the Dollar Equivalent of the face amount of all such Letters of Credit denominated in a Foreign Currency, plus, in each case, all interest, fees, and costs due or estimated by Bank to become due in connection therewith, to secure all of the Obligations relating to such Letters of Credit.

4. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants as follows:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

4.1 Due Organization, Authorization; Power and Authority.

(a) Borrower and each of its Subsidiaries are each duly existing and in good standing as a Registered Organization in their respective jurisdiction of formation and are qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of their respective business or their ownership of property requires that they be qualified except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business or operations.

(b) All information set forth on the Perfection Certificate pertaining to Borrower and each of its Subsidiaries is true and correct in all material respects (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent permitted by one or more specific provisions in this Agreement and the Perfection Certificate shall be deemed to be updated to the extent such notice is provided to Bank of such permitted update).

(c) The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or any such Subsidiary's organizational documents, (ii) contravene, conflict with, constitute a default under or violate any material Applicable Law, (iii) contravene, conflict with or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect), or (v) conflict with, contravene, constitute a default or breach under, or result in or permit the termination or acceleration of, any material agreement by which Borrower or any of its Subsidiaries is bound. Neither Borrower nor any of its Subsidiaries are in default under any agreement to which it is a party or by which it is bound in which the default could reasonably be expected to have a material adverse effect on Borrower's or any of its Subsidiary's business or operations.

4.2 Collateral.

(a) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject to Permitted Liens). Borrower has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens.

(b) Borrower has no Collateral Accounts at or with any bank or financial institution other than Bank or Bank's Affiliates except for the Collateral Accounts described in the Perfection Certificate delivered to Bank in connection herewith and which Borrower has taken such actions as are necessary to give Bank a perfected security interest therein, pursuant to the terms of Section 5.9(c). The Accounts are bona fide, existing obligations of the Account Debtors.

(c) The Collateral is not in the possession of any third party bailee (such as a warehouse) except as otherwise provided in the Perfection Certificate or as permitted pursuant to Section 6.2. None of the components of the Collateral shall be maintained at locations other than as provided in the Perfection Certificate or as permitted pursuant to Section 6.2.

(d) All Inventory is in all material respects of good quality, free from material defects.

(e) Borrower owns, or possesses the right to use to the extent necessary in its business, all Intellectual Property, licenses and other intangible assets that are used in the conduct of its business as now operated, except to the extent that such failure to own or possess the right to use such asset would not reasonably be expected to have a material adverse effect on Borrower's business or operations, and no such asset, to the best knowledge of Borrower, conflicts with the valid Intellectual Property, license, or intangible asset of any other Person to the extent that such conflict could reasonably be expected to have a material adverse effect on Borrower's business or operations.

(f) Except as noted on the Perfection Certificate or for which notice has been given to Bank pursuant to and in accordance with Section 5.11(c), Borrower is not a party to, nor is it bound by, any Restricted License.

4.3 Accounts Receivable; Inventory.

(a) For each Account included in the most recent Borrowing Base Statement, on the date each Advance is requested and made, such Account shall be an Eligible Account.

(b) All statements made and all unpaid balances appearing in all invoices, instruments and other documents evidencing the Eligible Accounts are and shall be true and correct in all material respects and all such invoices, instruments and other documents, and all of Borrower's Books are genuine and in all material respects what they purport to be. All sales and other transactions underlying or giving rise to each Eligible Account shall comply in all material respects with all Applicable Law. Borrower has no knowledge of any actual or imminent Insolvency Proceeding of any Account Debtor whose accounts are Eligible Accounts in any Borrowing Base Statement. To the best of Borrower's knowledge, all signatures and endorsements on all documents, instruments, and agreements relating to all Eligible Accounts are genuine, and all such documents, instruments and agreements are legally enforceable in accordance with their terms.

(c) For any item of Inventory relating to any Purchase Order included in any Borrowing Base Report, such Inventory (i) is not returned, consigned, obsolete, not sellable, damaged, or defective; (ii) meets all applicable governmental standards in all material respects; (iii) has been manufactured in compliance in all material respects with the Fair Labor Standards Act; (iv) is not subject to any Liens, except Permitted Liens; (v) such Inventory shall be located at the locations identified by Borrower in the Perfection Certificate where it maintains Inventory (or at any location permitted under Section 6.2) and, if such Inventory is located in the United States, Bank has received a landlord consent or bailee waiver, in form and substance reasonably satisfactory to Bank, in respect of such location to the extent required under Section 6.2; (vi) if such Inventory is in transit with a common carrier (whether located in the United States or otherwise), such Inventory shall be subject to a freight forwarder or carrier agreement, in form and substance reasonably satisfactory to Bank, duly executed by such carrier.

4.4 Litigation. Other than as set forth in the Perfection Certificate or as disclosed to Bank pursuant to Section 5.3(k), there are no actions, investigations or proceedings pending or, to the knowledge of any Responsible Officer, threatened in writing by or against Borrower or any of its Subsidiaries involving more than, individually or in the aggregate, Five Hundred Thousand Dollars ($500,000) not covered by independent third-party insurance as to which liability has been accepted by the carrier providing such insurance.

4.5 Financial Statements; Financial Condition. All consolidated financial statements for Borrower and any of its Subsidiaries delivered to Bank by submission to the Financial Statement Repository or otherwise submitted to Bank fairly present in all material respects Borrower's consolidated financial condition and Borrower's consolidated results of operations for the periods covered thereby, subject, in the case of unaudited financial statements, to normal year-end adjustments and the absence of footnote disclosures. There has not been any material deterioration in Borrower's consolidated financial condition since the date of the most recent financial statements submitted to the Financial Statement Repository or otherwise submitted to Bank.

4.6 Solvency. The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower and each of its Subsidiaries are able to pay their debts (including trade debts) as they mature.

4.7 Regulatory Compliance. Borrower is not an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Borrower is not engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries (a) have complied in all material respects with all Applicable Law, and (b) have not violated any Applicable Law the violation of which could reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower and each of its Subsidiaries have duly complied with, and their respective facilities, business, assets, property, leaseholds, real property and Equipment are in compliance with, Environmental Laws, except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business or operations; there have been no outstanding citations, notices or orders of non-compliance issued to Borrower or any of its Subsidiaries or relating to their respective facilities, businesses, assets, property, leaseholds, real property or Equipment under such Environmental Laws. Borrower and each of its Subsidiaries have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted, except where the failure to obtain or make or file the same would not reasonably be expected to have a material adverse effect on Borrower's business or operations.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

4.8 Subsidiaries; Investments. Borrower does not own any stock, partnership, or other ownership interest or other equity securities except for Permitted Investments.

4.9 Tax Returns and Payments; Pension Contributions.

(a) Borrower and each of its Subsidiaries have timely filed, or submitted extensions for, all required tax returns and reports, and Borrower and each of its Subsidiaries have timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower and each of its Subsidiaries except (i) to the extent such taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (ii) if such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Five Hundred Thousand Dollars ($500,000). Borrower is unaware of any claims or adjustments proposed for any of Borrower's or any of its Subsidiary's prior tax years which could result in additional taxes becoming due and payable by Borrower or any of its Subsidiaries in excess of Five Hundred Thousand Dollars ($500,000) in the aggregate.

(b) Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries has withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

4.10 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any report, certificate or written statement submitted to the Financial Statement Repository or otherwise submitted to Bank, as of the date such representation, warranty, or other statement was made, taken together with all such reports, certificates and written statements submitted to the Financial Statement Repository or otherwise submitted to Bank, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the reports, certificates or written statements not materially misleading in light of the circumstances under which they were made (it being recognized by Bank that the projections and forecasts provided by Borrower or any of its Subsidiaries in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may materially differ from the projected or forecasted results).

4.11 Sanctions. Neither Borrower nor any of its Subsidiaries is: (a) in violation of any Sanctions; or (b) a Sanctioned Person. Neither Borrower nor any of its Subsidiaries, directors, officers, employees, agents or Affiliates: (i) conducts any business or engages in any transaction or dealing with any Sanctioned Person, including making or receiving any contribution of funds, goods or services to or for the benefit of any Sanctioned Person; (ii) deals in, or otherwise engages in any transaction relating to, any property or interests in property blocked pursuant to any Sanctions; (iii) engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in any Sanctions; or (iv) otherwise engages in any transaction that could cause Bank to violate any Sanctions.

5. AFFIRMATIVE COVENANTS

Borrower shall do all of the following:

5.1 Use of Proceeds. Cause the proceeds of the Credit Extensions to be used solely (a) as working capital or (b) to fund its general business purposes, and not for personal, family, household or agricultural purposes.

5.2 Government Compliance.

(a) Maintain its and all of its Subsidiaries' legal existence (except as permitted under Section 6.2 or 6.3 with respect to Subsidiaries only) and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify would reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower shall comply, and have each Subsidiary comply, in all material respects, with all material laws, ordinances and regulations to which it is subject.

(b) Obtain all of the Governmental Approvals necessary for the performance by Borrower and each of its Subsidiaries of their obligations under the Loan Documents to which it is a party, including any grant of a security interest to Bank. Borrower shall promptly upon reasonable request provide copies of any such obtained Governmental Approvals to Bank.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.3 Financial Statements, Reports. Deliver to Bank by submitting to the Financial Statement Repository:

(a) Borrowing Base Statement. A Borrowing Base Statement (and any schedules related thereto and including any other information requested by Bank with respect to Borrower's Accounts) no later than thirty (30) days after the end of each month when a Streamline Period is not in effect and any Advances are outstanding;

(b) Accounts Receivable and Inventory Information. Within thirty (30) days after the end of each month when there are any outstanding Advances and a Streamline Period is not in effect, (i) monthly accounts receivable agings, aged by invoice date, (ii) monthly accounts payable agings, aged by invoice date, and outstanding or held check registers, if any, (iii) monthly reconciliations of accounts receivable agings (aged by invoice date), and general ledger;

(c) Monthly Financial Statements. As soon as available, but no later than thirty (30) days after the last day of each month when there is an outstanding balance under the Revolving Line, a company prepared consolidated and, if applicable, consolidating balance sheet and income statement covering Borrower's consolidated, and if applicable, Borrower's and each of its Subsidiary's, operations for such month in a form reasonably acceptable to Bank;

(d) Compliance Statement. Within thirty (30) days after the last day of each month when there is an outstanding balance under the Revolving Line, and together with the statements set forth in Section 5.3(c), a duly completed Compliance Statement, confirming that as of the end of such month, Borrower was in full compliance with all of the terms and conditions of this Agreement, and setting forth calculations showing compliance with the financial covenants set forth in this Agreement and such other information as Bank may reasonably request, including, without limitation, a statement that at the end of such month there were no held checks;

(e) Quarterly SEC Filings. As soon as available, and in any event within forty-five (45) days after the end of each of the first three (3) fiscal quarter of Borrower, and within ninety (90) days of fiscal year end, company prepared consolidated and, if applicable, consolidating balance sheet and income statement covering Borrower's consolidated and, if applicable, Borrower's and each of its Subsidiary's operations for such quarter in a form reasonably acceptable to Bank;

(f) Annual Operating Budget and Financial Projections. Within thirty (30) days after the end of each fiscal year of Borrower, and within seven (7) days of any updates or amendments thereto, (i) annual operating budgets (including income statements, balance sheets and cash flow statements, by month) for the then current fiscal year of Borrower, and (ii) annual financial projections for the then current fiscal year (on a quarterly basis), in each case as approved by the Board, together with any related business forecasts used in the preparation of such annual financial projections;

(g) Annual Audited Financial Statements. As soon as available, and in any event within ninety (90) days following the end of Borrower's fiscal year, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion (other than a going concern qualification based solely on the Obligations maturing within the next twelve (12) months) on the financial statements from an independent certified public accounting firm reasonably acceptable to Bank;

(h) SEC Filings. Within five (5) days of filing, notification of the filing and copies of all periodic and other reports, proxy statements and other materials filed by Borrower and/or any of its Subsidiaries or any Guarantor with the SEC, any Governmental Authority succeeding to any or all of the functions of the SEC or with any national securities exchange, or distributed to its shareholders, as the case may be;

(i) Security Holder and Subordinated Debt Holder Reports. Within five (5) days of delivery, copies of all material statements, reports and notices made available to Borrower's security holders or to any holders of Subordinated Debt (solely in their capacities as security holders or holders of Subordinated Debt and not in any other role);

(j) Beneficial Ownership Information. Prompt written notice of any changes to the beneficial ownership information set out in Section 14 of the Perfection Certificate. Borrower understands and acknowledges that Bank relies on such true, accurate and up-to-date beneficial ownership information to meet Bank's regulatory obligations to obtain, verify and record information about the beneficial owners of its legal entity customers;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(k) Legal Action Notice. Prompt written notice of any legal actions, investigations or proceedings pending or threatened in writing against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of, individually or in the aggregate, [*] or more;

(l) Tort Claim Notice. If Borrower shall acquire a commercial tort claim with a potential value in excess of Five Hundred Thousand Dollars ($500,000). Borrower shall promptly notify Bank in a writing signed by Borrower of the general details thereof and grant to Bank in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Bank;

(m) Account Statements. Promptly upon demand by Bank (and in any case within two (2) Business Days), account statements for all Collateral Accounts maintained outside Bank.

(n) Government Filings. Within five (5) days after the same are sent or received, copies of all correspondence, reports, documents and other filings by Borrower or any of its Subsidiaries with any Governmental Authority regarding compliance with or maintenance of Governmental Approvals or Applicable Law or that could reasonably be expected to have a material effect on any of the Governmental Approvals or otherwise on the business of Borrower or any of its Subsidiaries;

(o) Registered Organization. If Borrower is not a Registered Organization as of the Effective Date but later becomes one, promptly notify Bank of such occurrence and provide Bank with Borrower's organizational identification number;

(p) Default. Prompt written notice of the occurrence of a Default or Event of Default; and

(q) Other Information. Promptly, from time to time, such other information regarding Borrower or any of its Subsidiaries or compliance with the terms of any Loan Documents as reasonably requested by Bank.

Documents required to be delivered pursuant to the terms of this Section 5.3 (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower or any of its Subsidiaries posts such documents, or provides a link thereto, on Borrower's or any of its Subsidiaries' website on the internet at Borrower's or any of its Subsidiaries' website address or when such documents are filed with EDGAR.

Any submission by Borrower of a Compliance Statement, a Borrowing Base Statement or any other financial statement submitted to the Financial Statement Repository pursuant to this Section 5.3 or otherwise submitted to Bank shall be deemed to be a representation by Borrower that (i) as of the date of such Compliance Statement, Borrowing Base Statement or other financial statement, the information and calculations set forth therein are true and correct, (ii) as of the end of the compliance period set forth in such submission, Borrower is in complete compliance with all required covenants except as noted in such Compliance Statement, Borrowing Base Statement or other financial statement, as applicable, (iii) as of the date of such submission, no Events of Default have occurred or are continuing, (iv) all representations and warranties other than any representations or warranties that are made as of a specific date in Section 4 remain true and correct in all material respects as of the date of such submission except as noted in such Compliance Statement, Borrowing Base Statement or other financial statement, as applicable, (v) as of the date of such submission, Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 4.9, and (vi) as of the date of such submission, no Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank.

5.4 Accounts Receivable.

(a) Schedules and Documents Relating to Accounts. Borrower shall deliver to Bank transaction reports and schedules of collections, as provided in Section 5.3, on Bank's standard forms; provided, however, that Borrower's failure to execute and deliver the same shall not affect or limit Bank's Lien and other rights in all of Borrower's Accounts, nor shall Bank's failure to advance or lend against a specific Account affect or limit Bank's Lien and other rights therein. If requested by Bank, Borrower shall furnish Bank with copies (or, at Bank's request, originals) of all contracts, orders, invoices, and other similar documents, and all shipping instructions, delivery receipts, bills of lading, and other evidence of delivery, for any goods the sale or disposition of

which gave rise to such Accounts. In addition, Borrower shall deliver to Bank, on its request, the originals of all instruments, chattel paper, security agreements, guarantees and other documents and property evidencing or securing any Accounts, in the same form as received, with all necessary indorsements, and copies of all credit memos.

(b) Disputes. Borrower shall promptly notify Bank of all disputes or claims relating to Accounts in an amount in excess of Five Hundred Thousand Dollars ($500,000). Borrower may forgive (completely or partially), compromise, or settle any Account for less than payment in full, or agree to do any of the foregoing so long as (i) Borrower does so in good faith, in a commercially reasonable manner, in the ordinary course of business, in arm's-length transactions, and reports the same to Bank in the regular reports provided to Bank; (ii) no Event of Default has occurred and is continuing; and (iii) there shall not be an Overadvance after taking into account all such discounts, settlements and forgiveness.

(c) Collection of Accounts. Borrower shall direct Account Debtors to deliver or transmit all proceeds of Accounts into a lockbox account, or such other "blocked account" as specified by Bank (either such account, the "**Cash Collateral Account**"). Whether or not an Event of Default has occurred and is continuing, Borrower shall immediately deliver all payments on and proceeds of Accounts to the Cash Collateral Account. Subject to Bank's right to maintain a reserve pursuant to Section 5.4(d), all amounts received in the Cash Collateral Account shall be (i) when a Streamline Period is not in effect, applied to immediately reduce the Obligations under the Revolving Line (unless Bank, in its sole discretion, at times when an Event of Default exists, elects not to so apply such amounts), or (ii) when a Streamline Period is in effect, transferred on a daily basis to Borrower's operating account with Bank. Borrower hereby authorizes Bank to transfer to the Cash Collateral Account any amounts that Bank reasonably determines are proceeds of the Accounts (provided that Bank is under no obligation to do so and this allowance shall in no event relieve Borrower of its obligations hereunder).

(d) Reserves. Notwithstanding any terms in this Agreement to the contrary, (i) Bank may, in its good faith business judgment, hold any proceeds of the Accounts and any amounts in the Cash Collateral Account as a reserve to cover Borrower's Obligations to Bank (and to pay such Obligations when due); and (ii) at times when an Event of Default exists, Bank may hold any proceeds of the Accounts and any amounts in the Cash Collateral Account that are not applied to the Obligations pursuant to Section 5.4(c) above (including amounts otherwise required to be transferred to Borrower's operating account with Bank) as a reserve to be applied to any Obligations regardless of whether such Obligations are then due and payable.

(e) Returns. Provided no Event of Default has occurred and is continuing, if any Account Debtor returns any Inventory with a value in excess of Five Hundred Thousand Dollars ($500,000) to Borrower, Borrower shall promptly (i) determine the reason for such return, (ii) issue a credit memorandum to the Account Debtor in the appropriate amount in accordance with Borrower's customary business practices, and (iii) provide a copy of such credit memorandum to Bank, upon request from Bank. In the event any attempted return occurs after the occurrence and during the continuance of any Event of Default, Borrower shall hold the returned Inventory in trust for Bank, and immediately notify Bank of the return of the Inventory.

(f) Verifications; Confirmations; Credit Quality; Notifications. Bank may, from time to time, (i) verify and confirm directly with the respective Account Debtors the validity, amount and other matters relating to the Accounts, either in the name of Borrower or Bank or such other name as Bank may choose, and notify any Account Debtor of Bank's security interest in such Account; provided however so long as no Event of Default has occurred or is continuing Bank shall use commercially reasonable efforts to provide Borrower with prior notice thereof and/or (ii) conduct a credit check of any Account Debtor to approve any such Account Debtor's credit.

(g) No Liability. Bank shall not be responsible or liable for any shortage or discrepancy in, damage to, or loss or destruction of, any goods, the sale or other disposition of which gives rise to an Account, or for any error, act, omission, or delay of any kind occurring in the settlement, failure to settle, collection or failure to collect any Account, or for settling any Account in good faith for less than the full amount thereof, nor shall Bank be deemed to be responsible for any of Borrower's obligations under any contract or agreement giving rise to an Account. Nothing herein shall, however, relieve Bank from liability for its own gross negligence, bad faith or willful misconduct.

5.5 Remittance of Proceeds. Except as otherwise provided in Section 5.4(c), deliver, in kind, all proceeds arising from the disposition of any Collateral to Bank in the original form in which received by Borrower not later than the following Business Day after receipt by Borrower, to be applied to the Obligations (a) prior to an Event of Default, pursuant to the terms of Section 5.4(c) hereof, and (b) after the occurrence and during the continuance of an Event of Default, pursuant to the terms of Section 8.4 hereof; provided that, if no Event of Default has occurred and is continuing, Borrower shall not be obligated to remit to Bank the proceeds of the sale of worn out or obsolete Equipment disposed of by Borrower in good faith in an arm's length transaction for an aggregate purchase price of Five Hundred Thousand Dollars ($500,000) or less (for all such transactions in any

fiscal year) and other dispositions permitted by Section 6.1. Borrower agrees that it will deposit proceeds of Collateral in a Collateral Account and will hold such proceeds in an express trust for Bank. Nothing in this Section 5.5 limits the restrictions on disposition of Collateral set forth elsewhere in this Agreement.

5.6 Taxes; Pensions.

(a) Timely file, and require each of its Subsidiaries to timely file (in each case, unless subject to a valid extension), all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower and each of its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 4.9(a) hereof, and shall deliver to Bank, on demand, appropriate certificates attesting to such payments, and pay, and require each of its Subsidiaries to pay, all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms.

(b) To the extent Borrower or any of its Subsidiaries defers payment of contested taxes in an aggregate amount in excess of [*], Borrower shall (i) notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien."

5.7 Access to Collateral; Books and Records. At reasonable times, on five (5) Business Day's notice (provided no notice is required if an Event of Default has occurred and is continuing), Bank, or its agents, shall have the right to inspect the Collateral (subject to restrictions imposed by BARDA or applicable law) and the right to audit and copy Borrower's Books. Such inspections and audits shall be conducted no more often than twice every twelve (12) months, unless an Event of Default has occurred and is continuing, in which case such inspections and audits shall occur as often as Bank shall determine is necessary. The foregoing inspections and audits shall be conducted at Borrower's expense and the charge therefor shall be [*] per person per day (or such higher amount as shall represent Bank's then-current standard charge for the same), plus reasonable out-of-pocket expenses. In the event Borrower and Bank schedule an audit more than eight (8) days in advance, and Borrower cancels or seeks to or reschedules the audit with less than eight (8) days written notice to Bank, then (without limiting any of Bank's rights or remedies) Borrower shall pay Bank a fee of [*] plus any reasonable out-of-pocket expenses incurred by Bank to compensate Bank for the anticipated costs and expenses of the cancellation or rescheduling. The Initial Audit shall be completed after completion of one full BARDA procurement cycle.

5.8 Insurance.

(a) Keep its business and the Collateral insured for risks and in amounts standard for companies in Borrower's industry and location and as Bank may reasonably request. Insurance policies shall be in a form, with financially sound and reputable insurance companies that are not Affiliates of Borrower, and in amounts that are satisfactory to Bank.

(b) All property policies shall have a lender's loss payable endorsement showing Bank as lender loss payee. All liability policies shall show, or have endorsements showing, Bank as an additional insured. Bank shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral.

(c) Ensure that proceeds payable under any property policy are, at Bank's option, payable to Bank on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to [*] in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Bank has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Bank, be payable to Bank on account of the Obligations.

(d) At Bank's request, Borrower shall deliver certified copies of insurance policies and evidence of all premium payments. Each provider of any such insurance required under this Section 5.8 shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Bank, that it will give Bank thirty (30) days prior written notice before any such policy or policies shall be canceled. If Borrower fails to obtain insurance as required under this Section 5.8 or to pay any amount or furnish any required proof of payment to third persons and Bank, Bank may make all or part of such payment or obtain such insurance policies required in this Section 5.8, and take any action under the policies Bank deems prudent.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.9 Accounts.

(a) Maintain account balances in Borrower's, any of its Subsidiaries', and any Guarantor's operating accounts and depository accounts at or through Bank representing at least fifty percent (50%) of the Dollar Equivalent value of all deposit account balances of Borrower, such Subsidiary and such Guarantor at all financial institutions.

(b) In addition to the foregoing, Borrower, any domestic Subsidiary of Borrower and any Guarantor, shall obtain any business credit card, letter of credit and cash management services exclusively from Bank other than credit cards permitted under clause (h) of the definition of Permitted Indebtedness. Any foreign Subsidiary of Borrower shall use commercially reasonable efforts to obtain any business credit card, letter of credit and cash management services from Bank.

(c) In addition to and without limiting the restrictions in (a), Borrower shall provide Bank five (5) days prior written notice before establishing any Collateral Account at or with any bank or financial institution other than Bank or Bank's Affiliates. For each Collateral Account that Borrower at any time maintains, Borrower shall cause the applicable bank or financial institution (other than Bank) at or with which any Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Bank's Lien in such Collateral Account in accordance with the terms hereunder which Control Agreement may not be terminated without the prior written consent of Bank. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit payments to or for the benefit of Borrower's employees and identified to Bank by Borrower as such.

5.10 Financial Covenants. At all times when there is an outstanding balance under the Revolving Line and a Streamline Period is not in effect, maintain:

(a) Liquidity equal to or greater than (A) the greater of (i) [*] the sum of (I) outstanding Advances based on ABPO plus (II) the aggregate dollar amount of all outstanding Advances based on Purchase Orders or (ii) the sum of (I) outstanding Advances based on ABPO plus (II) the aggregate dollar amount of all outstanding Advances based on Purchase Orders plus (III) trailing [*] Cash Burn plus (B), at all times until completion of the Initial Audit, [*] the amount of Borrower's outstanding Advances based on Accounts receivable; and

(b) Unrestricted cash at Bank or in accounts subject to a Control Agreement in favor of Bank not less than the sum of (I) outstanding Advances based on ABPO plus (II) the aggregate dollar amount of all outstanding Advances based on Purchase Orders.

5.11 Protection of Intellectual Property Rights.

(a) (i) Protect, defend and maintain the validity and enforceability of Borrower's and each Subsidiary's Intellectual Property, except to the extent that such failure to do so would not reasonably be expected to have a material adverse effect on Borrower's business or operations; (ii) promptly advise Bank in writing of material infringements or any other event that could reasonably be expected to materially and adversely affect the value Borrower's and each Subsidiary's Intellectual Property that has any material value; and (iii) not allow any Intellectual Property material to Borrower's or any Subsidiary's business to be abandoned, forfeited or dedicated to the public without Bank's written consent.

(b) Provide written notice to Bank within thirty (30) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Borrower shall take such steps as Bank requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any such Restricted License to be deemed "Collateral" and for Bank to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) Bank to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Bank's rights and remedies under this Agreement and the other Loan Documents.

5.12 Litigation Cooperation. From the date hereof and continuing through the termination of this Agreement, make available to Bank, without expense to Bank, Borrower and its officers, employees and agents and Borrower's books and records, to the extent that Bank may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Bank with respect to any Collateral or relating to Borrower.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.13 Online Banking.

(a) Utilize Bank's online banking platform for all matters requested by Bank which shall include, without limitation (and without request by Bank for the following matters), uploading information pertaining to Accounts and Account Debtors, requesting approval for exceptions, requesting Credit Extensions, and uploading financial statements and other reports required to be delivered by this Agreement (including, without limitation, those described in Section 5.3 of this Agreement).

(b) Comply with the terms of Bank's Online Banking Agreement as in effect from time to time and ensure that all persons utilizing Bank's online banking platform are duly authorized to do so by an Administrator. Bank shall be entitled to assume the authenticity, accuracy and completeness of any information, instruction or request for a Credit Extension submitted via Bank's online banking platform and to further assume that any submissions or requests made via Bank's online banking platform have been duly authorized by an Administrator.

5.14 Formation or Acquisition of Subsidiaries. Notwithstanding and without limiting the negative covenants contained in Sections 6.3 and 6.7 hereof, at the time that Borrower or any Guarantor forms any Subsidiary or acquires any Subsidiary after the Effective Date (including, without limitation, pursuant to a Division), Borrower and such Guarantor shall (a) cause such new Subsidiary to provide to Bank a joinder to this Agreement to become a co-borrower hereunder or a guaranty to become a Guarantor hereunder (as determined by Bank in its sole discretion), together with documentation, all in form and substance satisfactory to Bank (including being sufficient to grant Bank a first priority Lien (subject to Permitted Liens) in and to the assets of such newly formed or acquired Subsidiary), (b) provide to Bank appropriate certificates and powers and financing statements, pledging all of the direct or beneficial ownership interest in such new Subsidiary, in form and substance satisfactory to Bank; and (c) provide to Bank all other documentation in form and substance satisfactory to Bank which in its opinion is appropriate with respect to the execution and delivery of the applicable documentation referred to above. Any document, agreement, or instrument executed or issued pursuant to this Section 5.14 shall be a Loan Document. Notwithstanding the foregoing, Borrower shall not be required to cause any foreign Subsidiary of Borrower formed or acquired after the Effective Date to comply with this Section 5.14 to the extent any such foreign Subsidiary has less than 10% of Borrower's consolidated revenues and consolidated assets.

5.15 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower and its Account Debtors shall follow Borrower's customary practices as they exist at the Effective Date. Borrower shall promptly notify Bank of all returns, recoveries, disputes and claims that involve more than Five Hundred Thousand Dollars ($500,000).

5.16 Further Assurances. Execute any further instruments and take such further action as Bank reasonably requests to perfect, protect, ensure the priority of or continue Bank's Lien on the Collateral or to effect the purposes of this Agreement.

5.17 Sanctions. (a) Not, and not permit any of its Subsidiaries to, engage in any of the activities described in Section 4.11 in the future; (b) not, and not permit any of its Subsidiaries to, become a Sanctioned Person; (c) ensure that the proceeds of the Obligations are not used to violate any Sanctions; and (d) deliver to Bank any certification or other evidence requested from time to time by Bank in its sole discretion, confirming each such Person's compliance with this Section 5.19. In addition, have implemented, and will consistently apply while this Agreement is in effect, procedures to ensure that the representations and warranties in Section 4.11 remain true and correct while this Agreement is in effect.

5.18 Post-Closing Matters. Deliver to Bank, within forty-five (45) days of the Effective Date, each of the following, in form and substance acceptable to Bank:

(a) duly executed landlord's consent in favor of Bank for each of Borrower's leased locations in the United States where more than [*] in Collateral is maintained, by the respective landlord thereof (excluding Inventory or other property held with contract manufacturers; and

(b) duly executed bailee's waiver in favor of Bank for each location in the United States where Borrower maintains Inventory or other property with a third party with a value in excess of [*] (excluding Inventory or other property held with contract manufacturers), by each such third party.

6. NEGATIVE COVENANTS

Borrower shall not do any of the following without Bank's prior written consent:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business (including, for the avoidance of doubt, pursuant to compassionate use and emergency use requests and clinical trials); (b) of worn-out, surplus or obsolete Equipment that is, in the reasonable judgment of Borrower, no longer economically practicable to maintain or useful in the ordinary course of business of Borrower; (c) consisting of Permitted Liens and Permitted Investments; (d) consisting of the sale or issuance of any stock, partnership, membership, or other ownership interest or other equity securities of Borrower permitted under Section 6.2 of this Agreement; (e) consisting of Borrower's or its Subsidiaries' use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; (f) Permitted Licenses, (g) of Intellectual Property that has no material value; (h) other Transfers not otherwise permitted in clauses (a) through (g) above involving tangible assets of Borrower (but specifically excluding any Transfers of Accounts, monthly recurring revenue, annual recurring revenue or any other recurring revenue of Borrower in any factoring, sale-leaseback, future receipts purchase agreement or other similar agreement) having a fair market value of not more than Five Hundred Thousand Dollars ($500,000) in the aggregate in any fiscal year so long as no Event of Default has occurred or would occur immediately following any such Transfer(i) Transfers from Borrower to its Subsidiaries that constitute a Permitted Investment and (j) Transfers from any Subsidiary to Borrower.

6.2 Changes in Business, Management, Control, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower and such Subsidiary, as applicable, or reasonably related thereto; (b) liquidate or dissolve or permit any of its Subsidiaries to liquidate or dissolve (except as permitted by Section 6.3); provided that any Subsidiary of the Borrower may liquidate, wind-up or dissolve itself as long as substantially all of its assets are transferred to the Borrower or a Guarantor; (c) fail to provide notice to Bank of any Key Person departing from or ceasing to be employed by Borrower within ten (10) days after their departure from Borrower; (d) permit, allow or suffer to occur any Change in Control; or (e) without at least thirty (30) days prior written notice to Bank, (i) add any new offices or business locations in the United States, including warehouses (unless such new offices or business locations contain less than [*] in Borrower's assets or property (excluding tenant improvements)) or deliver any portion of the Collateral valued, individually or in the aggregate, in excess of [*] to a bailee at a location in the United States other than to a bailee and at a location already disclosed in the Perfection Certificate (excluding Inventory or other property held with contract manufacturers), (ii) change its jurisdiction of organization, (iii) change its organizational structure or type, (iv) change its legal name, or (v) change any organizational number (if any) assigned by its jurisdiction of organization. If Borrower intends to add any new offices or business locations in the United States, including warehouses, containing in excess of [*] of Borrower's assets or property (excluding Inventory or other property held with contract manufacturers), then Borrower will cause the landlord of any such new offices or business locations, including warehouses, to execute and deliver a landlord consent in form and substance reasonably satisfactory to Bank. If Borrower intends to deliver any portion of the Collateral valued, individually or in the aggregate, in excess of [*] to a bailee in the United States (excluding Inventory or other property held with contract manufacturers), and Bank and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Borrower intends to deliver the Collateral, then Borrower will cause such bailee to execute and deliver a bailee agreement in form and substance reasonably satisfactory to Bank..

6.3 Mergers or Acquisitions. Except for Permitted Acquisitions, merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the stock, partnership, membership, or other ownership interest or other equity securities or property of another Person (including, without limitation, by the formation of any Subsidiary or pursuant to a Division). A Subsidiary may merge or consolidate into another Subsidiary or into Borrower.

6.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

6.5 Encumbrance. Create, incur, allow, or suffer to exist any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, permit any Collateral not to be subject to the first priority security interest granted herein, or enter into any agreement, document, instrument or other arrangement (except with or in favor of Bank) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower or any Subsidiary from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or any Subsidiary's Intellectual Property, except as is otherwise permitted in Section 6.1 hereof and the definition of "Permitted Liens" herein.

6.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 5.9(c).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.7 Distributions; Investments. (a) Pay any dividends or make any distribution or payment or redeem, retire or purchase any stock, partnership, membership, or other ownership interest or other equity securities provided that Borrower may (i) convert or exchange any of its convertible securities into or for other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof, (ii) pay dividends solely in equity, (iii) repurchase the stock, partnership, membership, or other ownership interest or other equity securities of former employees, officers, directors or consultants pursuant to employee stock purchase plans, stockholder plans, director or consultant stock option plans, employee stock option agreements, restricted stock agreements, equity incentive plans or other similar agreements or plans so long as an Event of Default does not exist at the time of any such repurchase and would not exist after giving effect to any such repurchase, provided that the aggregate amount of all such repurchases does not exceed [*] per fiscal year, (iv) make de minimis payments in lieu of fractional shares, (v) purchases of capital stock or options, warrants or other agreements to acquire such capital stock with the proceeds received from a substantially concurrent issuance of capital stock or convertible securities; provided that such purchases do not exceed [*] in the aggregate per fiscal year, (vi) purchases of capital stock pledged as collateral for loans to employees; provided that such purchases do not exceed [*] in the aggregate per fiscal year, (vii) purchases of capital stock in connection with the exercise of stock options, warrants or other equity awards by way of cashless exercise or in connection with the satisfaction of withholding tax obligations, (viii) purchases of fractional shares of capital stock arising out of stock dividends, splits or combinations or business combinations or in connection with exercises or conversions of options, warrants and other convertible securities, (ix) dividends and distributions by any Subsidiary to Borrower or another Subsidiary that is a co-Borrower or a Guarantor and (x) purchases for value of any rights distributed in connection with any stockholder rights plan; or (b) directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments, or permit any of its Subsidiaries to do so.

6.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower, except for (a) transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person, (b) transactions between Borrower and a Subsidiary that is permitted under Section 6.7, (c) reasonable and customary compensation arrangements and benefit plans for officers and other employees of Borrower approved by the Board, and (d) reasonable and customary fees paid to independent members of the Board in the ordinary course of business.

6.9 Subordinated Debt. Except as expressly permitted under the terms of the subordination, intercreditor, or other similar agreement to which any Subordinated Debt is subject: (a) make or permit any payment on such Subordinated Debt; or (b) amend any provision in any document relating to such Subordinated Debt which would increase the amount thereof, provide for earlier or greater principal, interest, or other payments thereon, or adversely affect the subordination thereof to Obligations owed to Bank.

6.10 Compliance. (a) Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; (b)(i) fail to meet the minimum funding requirements of ERISA, (ii) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur, (iii) fail to comply with the Federal Fair Labor Standards Act or (iv) violate any other law or regulation, if the foregoing subclauses (i) through (iv), individually or in the aggregate, could reasonably be expected to have a material adverse effect on Borrower's business or operations, or permit any of its Subsidiaries to do so; or (c) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

6.11 Subsidiary Assets. Permit the value of any assets held at Borrower's Subsidiaries that are not a Borrower or Guarantor hereunder to exceed [*] at any time.

7. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

7.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day cure period shall not apply to payments due on the Revolving Line Maturity Date). During the cure period, the failure to make or pay any payment specified under clause (b) hereunder is not an Event of Default (but no Credit Extension will be made during the cure period);

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.2 Covenant Default.

(a) Borrower fails or neglects to perform any obligation in Section 5 (other than Sections 5.2 (Government Compliance), 5.12 (Litigation Cooperation), 5.17 (Inventory; Returns) and 5.18 (Further Assurances)) or violates any covenant in Section 6; or

(b) Borrower fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 7) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Cure periods provided under this section shall not apply, among other things, to financial covenants or any other covenants that are required to be satisfied, completed or tested by a date certain or any covenants set forth in clause (a) above;

7.3 Material Adverse Change. A Material Adverse Change occurs;

7.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any Subsidiary, or (ii) a notice of lien or levy is filed against any of Borrower's or any of its Subsidiaries' assets by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; or

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting all or any material part of its business;

7.5 Insolvency. (a) Borrower or any of its Subsidiaries is unable to pay its debts (including trade debts) as they become due or otherwise becomes insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and is not dismissed or stayed within thirty (30) days (but no Credit Extensions shall be made while any of the conditions described in clause (a) exist or until any Insolvency Proceeding is dismissed);

7.6 Other Agreements. There is, under any agreement to which Borrower, any of Borrower's Subsidiaries, or any Guarantor is a party with a third party or parties, (a) any default resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount individually or in the aggregate in excess of [*]; or (b) any breach or default by Borrower, any of Borrower's Subsidiaries, or Guarantor, the result of which could have a material adverse effect on Borrower's, any of Borrower's Subsidiaries', or any Guarantor's business or operations;

7.7 Judgments; Penalties. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least [*] (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries by any Governmental Authority, and the same are not, within ten (10) days after the entry, assessment or issuance thereof, discharged, or after execution thereof, or stayed pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the discharge, or stay of such fine, penalty, judgment, order or decree);

7.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Bank or to induce Bank to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made (it being agreed and acknowledged by Bank that the projections and forecasts provided by Borrower or any of its Subsidiaries in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may materially differ from the projected or forecasted results);

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.9 Subordinated Debt. If: (a) any document, instrument, or agreement evidencing any Subordinated Debt shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, or any Person (other than Bank) shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further liability or obligation thereunder; (b) a default or event of default (however defined) has occurred under any document, instrument, or agreement evidencing any Subordinated Debt, which default shall not have been cured or waived within any applicable grace period; or (c) the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement or any applicable subordination or intercreditor agreement;

7.10 Lien Priority. There is a material impairment in the perfection or priority of Bank's security interest in the Collateral;

7.11 Guaranty. (a) Any guaranty of any Obligations terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any guaranty of the Obligations; (c) any circumstance described in Sections 7.3, 7.4, 7.5, 7.6, 7.7, or 7.8 of this Agreement occurs with respect to any Guarantor, (d) the death, liquidation, winding up, or termination of existence of any Guarantor; or (e)(i) a material impairment in the perfection or priority of Bank's Lien in the collateral provided by Guarantor or in the value of such collateral or (ii) a material adverse change in the general affairs, management, results of operation, condition (financial or otherwise) or the prospect of repayment of the Obligations occurs with respect to any Guarantor; or

7.12 Governmental Approvals. Any Governmental Approval shall have been (a) revoked, rescinded, suspended, modified in a materially adverse manner or not renewed in the ordinary course for a full term or (b) subject to any decision by a Governmental Authority that designates a hearing with respect to any applications for renewal of any of such Governmental Approval or that could result in the Governmental Authority taking any of the actions described in clause (a) above, and such decision or such revocation, rescission, suspension, modification or non-renewal (i) causes, or could reasonably be expected to cause, a Material Adverse Change, or (ii) materially adversely affects the legal qualifications of Borrower or any of its Subsidiaries to hold such Governmental Approval in any applicable jurisdiction and such revocation, rescission, suspension, modification or non-renewal could reasonably be expected to affect the status of or legal qualifications of Borrower or any of its Subsidiaries to hold any Governmental Approval in any other jurisdiction.

8. BANK'S RIGHTS AND REMEDIES

8.1 Rights and Remedies. Upon the occurrence and during the continuance of an Event of Default, Bank may, without notice or demand, do any or all of the following:

(a) declare all Obligations immediately due and payable (but if an Event of Default described in Section 7.5 occurs all Obligations are immediately due and payable without any action by Bank);

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Bank;

(c) demand that Borrower (i) deposit cash with Bank in an amount equal to at least (A) [*] of the aggregate face amount of any Letters of Credit denominated in Dollars remaining undrawn, and (B) [*] of the Dollar Equivalent of the aggregate face amount of any Letters of Credit denominated in a Foreign Currency remaining undrawn (plus, in each case, all interest, fees, and costs due or estimated by Bank to become due in connection therewith), to secure all of the Obligations relating to such Letters of Credit, as collateral security for the repayment of any future drawings under such Letters of Credit, and Borrower shall forthwith deposit and pay such amounts, and (ii) pay in advance all letter of credit fees scheduled to be paid or payable over the remaining term of any Letters of Credit;

(d) terminate any FX Contracts (it being understood and agreed that (i) Bank is not obligated to deliver the currency which Borrower has contracted to receive under any FX Contract, and Bank may cover its exposure for any FX Contracts by purchasing or selling currency in the interbank market as Bank deems appropriate; (ii) Borrower shall be liable for all losses, damages, costs, margin obligations and expenses incurred by Bank arising from Borrower's failure to satisfy its obligations under any FX Contract or the execution of any FX Contract; and (iii) Bank shall not be liable to Borrower for any gain in value of a FX Contract that Bank may obtain in covering Borrower's breach);

(e) verify the amount of, demand payment of and performance under, and collect any Accounts and General Intangibles, settle or adjust disputes and claims directly with Account Debtors for amounts on

terms and in any order that Bank considers advisable, and notify any Person owing Borrower money of Bank's security interest in such funds. Borrower shall collect all payments in trust for Bank and, if requested by Bank, immediately deliver the payments to Bank in the form received from the Account Debtor, with proper endorsements for deposit;

(f) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Bank requests and make it available as Bank designates. Bank may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Bank a license to enter and occupy any of its premises, without charge, to exercise any of Bank's rights or remedies;

(g) apply to the Obligations any (i) balances and deposits of Borrower it holds, or (ii) amount held by Bank owing to or for the credit or the account of Borrower;

(h) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. For use solely upon the occurrence and during the continuation of an Event of Default, Bank is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's labels, Patents, Copyrights, mask works, rights of use of any name, trade secrets, trade names, Trademarks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section 8.1, Borrower's rights under all licenses and all franchise agreements inure to Bank's benefit;

(i) place a "hold" on any account maintained with Bank and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(j) demand and receive possession of Borrower's Books; and

(k) exercise all rights and remedies available to Bank under the Loan Documents or at law or equity, including all remedies provided under the Code or any Applicable Law (including disposal of the Collateral pursuant to the terms thereof).

8.2 Power of Attorney. Borrower hereby irrevocably appoints Bank as its true and lawful attorney-in-fact, (a) exercisable upon the occurrence and during the continuance of an Event of Default, to: (i) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; (ii) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (iii) demand, collect, sue, and give releases to any Account Debtor for monies due, settle and adjust disputes and claims about the Accounts directly with Account Debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Bank's or Borrower's name, as Bank chooses); (iv) make, settle, and adjust all claims under Borrower's insurance policies; (v) pay, contest or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (vi) transfer the Collateral into the name of Bank or a third party as the Code permits; and (vii) receive, open and dispose of mail addressed to Borrower; and (b) regardless of whether an Event of Default has occurred, to: (i) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; (ii) notify all Account Debtors to pay Bank directly; and (iii) sign Borrower's name on any documents necessary to perfect or continue the perfection of Bank's security interest in the Collateral. Bank's foregoing appointment as Borrower's attorney in fact, and all of Bank's rights and powers, coupled with an interest, are irrevocable until such time as all Obligations (other than inchoate indemnity obligations) have been satisfied in full, Bank is under no further obligation to make Credit Extensions and the Loan Documents have been terminated. Bank shall not incur any liability in connection with or arising from the exercise of such power of attorney and shall have no obligation to exercise any of the foregoing rights and remedies.

8.3 Protective Payments. If Borrower fails to obtain the insurance called for by Section 5.8 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Bank may obtain such insurance or make such payment, and all amounts so paid by Bank are Bank Expenses and immediately due and payable, bearing interest at the then highest rate applicable to the Obligations, and secured by the Collateral. Bank will make reasonable efforts to provide Borrower with notice of Bank obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Bank are deemed an agreement to make similar payments in the future or Bank's waiver of any Event of Default.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8.4 Application of Payments and Proceeds. If an Event of Default has occurred and is continuing, Bank may apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Accounts or other disposition of the Collateral, or otherwise, to the Obligations in such order as Bank shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Bank for any deficiency. If Bank, in its commercially reasonable business discretion, directly or indirectly, enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, Bank shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by Bank of cash therefor.

8.5 Bank's Liability for Collateral. Bank's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession or under its control, under Section 9-207 of the Code or otherwise, shall be to deal with it in the same manner as Bank deals with its own property consisting of similar instruments or interests. Borrower bears all risk of loss, damage or destruction of the Collateral.

8.6 No Waiver; Remedies Cumulative. Bank's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Bank thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Bank's rights and remedies under this Agreement and the other Loan Documents are cumulative. Bank has all rights and remedies provided under the Code, by law, or in equity. Bank's exercise of one right or remedy is not an election and shall not preclude Bank from exercising any other remedy under this Agreement or other remedy available at law or in equity, and Bank's waiver of any Event of Default is not a continuing waiver. Bank's delay in exercising any remedy is not a waiver, election, or acquiescence.

8.7 Demand Waiver. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Bank on which Borrower is liable.

9. NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address or email address indicated below; provided that, for clause (b), if such notice, consent, request, approval, demand or other communication is not sent during the normal business hours of the recipient, it shall be deemed to have been sent at the opening of business on the next Business Day of the recipient. Bank or Borrower may change its mailing or electronic mail address by giving the other party written notice thereof in accordance with the terms of this Section 9.

If to Borrower: CHIMERIX, INC.
2505 Meridian Parkway, Suite 100
Durham, NC 27713
[*]
[*]

If to Bank: Silicon Valley Bank
275 Grove Street, Suite 2-200
Newton, MA 02466
[*]
[*]

with a copy to (which shall not constitute notice):

DLA Piper LLP (US)
401 B Street, Suite 1700
San Diego, CA 92101-4297
[*]
[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

10. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

Except as otherwise expressly provided in any of the Loan Documents, California law governs the Loan Documents without regard to principles of conflicts of law that would require the application of the laws of another jurisdiction. Borrower and Bank each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in California; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Bank from bringing suit or taking other legal action in any other jurisdiction with respect to the Loan Documents or to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Bank. Borrower expressly, irrevocably and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby irrevocably and unconditionally waives, to the fullest extent permitted by Applicable Law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER AND BANK EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES HERETO TO ENTER INTO THIS AGREEMENT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

This Section 10 shall survive the termination of this Agreement and the repayment of all Obligations.

11. GENERAL PROVISIONS

11.1 Termination Prior to Maturity Date; Survival. All covenants, representations and warranties made in this Agreement shall continue in full force until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations) have been satisfied. So long as Borrower has satisfied the Obligations (other than inchoate indemnity obligations, and any other obligations which, by their terms, are to survive the termination of this Agreement and the repayment of all Obligations, and any Obligations under Bank Services Agreements that are cash collateralized in accordance with Section 3.1 of this Agreement), this Agreement may be terminated prior to the Revolving Line Maturity Date by Borrower, effective three (3) Business Days after

written notice of termination is given to Bank. Those obligations that are expressly specified in this Agreement as surviving this Agreement's termination and the repayment of all Obligations shall continue to survive notwithstanding this Agreement's termination and the repayment of all Obligations.

11.2 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not assign or transfer this Agreement or any rights or obligations under it without Bank's prior written consent (which may be granted or withheld in Bank's sole discretion) and any other attempted assignment or transfer by Borrower shall be null and void. Bank has the right, without the consent of or notice to Borrower, to sell, transfer, assign, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights, and benefits under this Agreement and the other Loan Documents. Notwithstanding the foregoing, so long as no Event of Default shall have occurred and is continuing, Bank shall not assign its interests in the Loan Documents to any Person who, in the reasonable estimation of Bank, is (a) a direct competitor of Borrower or (b) a vulture fund or distressed debt fund.

11.3 Indemnification.

(a) General Indemnification. Borrower shall indemnify, defend and hold Bank and its Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of Bank and its Affiliates (each, an "**Indemnified Person**") harmless against: all losses, claims, damages, liabilities and related expenses (including Bank Expenses and the reasonable fees, charges and disbursements of any counsel for any Indemnified Person) (collectively, "**Claims**") arising out of, in connection with, or as a result of (i) the execution or delivery of this Agreement, any other Loan Document or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder or the consummation of the transactions contemplated hereby or thereby, (ii) any Credit Extension or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of hazardous materials on or from any property owned or operated by Borrower or any of its Subsidiaries, or any environmental liability related in any way to Borrower or any of its Subsidiaries, or (iv) any actual or prospective claim, litigation, investigation or proceeding relating to any of the foregoing, whether based on contract, tort or any other theory, whether brought by a third party or by Borrower, and regardless of whether any Indemnified Person is a party thereto; provided that such indemnity shall not, as to any Indemnified Person, be available to the extent that such losses, claims, damages, liabilities or related expenses are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from the gross negligence or willful misconduct of such Indemnified Person. All amounts due under this Section 11.3 shall be payable promptly after demand therefor.

(b) Waiver of Consequential Damages, Etc. To the fullest extent permitted by Applicable Law, Borrower shall not assert, and hereby waives, any claim against any Indemnified Person, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) or any loss of profits arising out of, in connection with, or as a result of, this Agreement, any other Loan Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Credit Extension, or the use of the proceeds thereof. No Indemnified Person shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby.

This Section 11.3 shall survive the termination of this Agreement and the repayment of all Obligations until all statutes of limitation with respect to the Claims, losses, and expenses for which indemnity is given shall have run.

11.4 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

11.5 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

11.6 Amendments in Writing; Waiver; Integration. No purported amendment or modification of any Loan Document, or waiver, discharge or termination of any obligation under any Loan Document, shall be effective unless, and only to the extent, expressly set forth in a writing signed by each party hereto. Without limiting the generality of the foregoing, no oral promise or statement, nor any action, inaction, delay, failure to require performance or course of conduct shall operate as, or evidence, an amendment, supplement or waiver or have any other effect on any Loan Document. Any waiver granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver. The Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of the Loan Documents merge into the Loan Documents.

11.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed signature page of this Agreement by electronic mail transmission shall be effective as delivery of a manually executed counterpart hereof.

11.8 Confidentiality. Bank agrees to maintain the confidentiality of Information (as defined below), except that Information may be disclosed (a) to Bank's Subsidiaries and Affiliates and their respective employees, directors, agents, attorneys, accountants and other professional advisors (collectively, "**Representatives**" and, together with Bank, collectively, "**Bank Entities**"); (b) to prospective transferees, assignees, credit providers or purchasers of Bank's interests under or in connection with this Agreement and their Representatives (provided, however, Bank shall use commercially reasonable efforts to obtain any such prospective transferee's, assignee's, credit provider's, purchaser's or their Representatives' agreement to the terms of this provision); (c) as required by law, regulation, subpoena, or other order; (d) to Bank's regulators or as otherwise required or requested in connection with Bank's examination or audit; (e) in connection with the exercise of remedies under the Loan Documents or any action or proceeding relating to this Agreement or any other Loan Document or the enforcement of rights hereunder or thereunder; and (f) to third-party service providers of Bank so long as such service providers have executed a confidentiality agreement with Bank with terms no less restrictive than those contained herein. "**Information**" means all information received from Borrower regarding Borrower or its business, in each case other than information that is either: (i) in the public domain or in Bank's possession when disclosed to Bank, or becomes part of the public domain (other than as a result of its disclosure by Bank in violation of this Agreement) after disclosure to Bank; or (ii) disclosed to Bank by a third party, if Bank does not know that the third party is prohibited from disclosing the information.

11.9 Electronic Execution of Documents. The words "execution," "signed," "signature" and words of like import in any Loan Document shall be deemed to include electronic signatures, including any Electronic Signature as defined in the Electronic Transactions Law (2003 Revision) of the Cayman Islands (the "**Cayman Islands Electronic Signature Law**"), if applicable, or the keeping of records in electronic form, including any Electronic Record, as defined in Cayman Islands Electronic Signature Law, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any Applicable Law, including, without limitation, any state law based on the Uniform Electronic Transactions Act or the Cayman Islands Electronic Signature Law; provided, however that sections 8 and 19(3) of the Cayman Islands Electronic Signature Law shall not apply to this Agreement or the execution or delivery thereof.

11.10 Right of Setoff. Borrower hereby grants to Bank a Lien and a right of setoff as security for all Obligations to Bank, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Bank or any entity under the control of Bank (including a subsidiary of Bank) or in transit to any of them, and other obligations owing to Bank or any such entity. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Bank may setoff the same or any part thereof and apply the same to any liability or Obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE BANK TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER, ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

11.11 Captions and Section References. The headings used in this Agreement are for convenience only and shall not affect the interpretation of this Agreement. Unless indicated otherwise, section references herein are to sections of this Agreement.

11.12 Construction of Agreement. The parties hereto mutually acknowledge that they and their attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty this Agreement shall be construed without regard to which of the parties caused the uncertainty to exist.

11.13 Relationship. The relationship of the parties to this Agreement is determined solely by the provisions of this Agreement. The parties do not intend to create any agency, partnership, joint venture, trust, fiduciary or other relationship with duties or incidents different from those of parties to an arm's-length contract.

11.14 Third Parties. Nothing in this Agreement, whether express or implied, is intended to: (a) confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective permitted successors and assigns; (b) relieve or discharge the obligation or liability of any

Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

11.15 Anti-Terrorism Law. Bank hereby notifies Borrower that, pursuant to the requirements of Anti-Terrorism Law, Bank may be required to obtain, verify and record information that identifies Borrower, which information may include the name and address of Borrower and other information that will allow Bank to identify Borrower in accordance with Anti-Terrorism Law. Borrower hereby agrees to take any action necessary to enable Bank to comply with the requirements of Anti-Terrorism Law.

12. ACCOUNTING TERMS AND OTHER DEFINITIONS

12.1 Accounting and Other Terms.

(a) Accounting terms not defined in this Agreement shall be construed following GAAP. Calculations and determinations must be made following GAAP (except for with respect to unaudited financial statements for the absence of footnotes and subject to year-end audit adjustments), provided that if at any time any change in GAAP would affect the computation of any financial ratio or requirement set forth in any Loan Document, and either Borrower or Bank shall so request, Borrower and Bank shall negotiate in good faith to amend such ratio or requirement to preserve the original intent thereof in light of such change in GAAP; provided, further, that, until so amended, (i) such ratio or requirement shall continue to be computed in accordance with GAAP prior to such change therein and (ii) Borrower shall provide Bank financial statements and other documents required under this Agreement or as reasonably requested hereunder setting forth a reconciliation between calculations of such ratio or requirement made before and after giving effect to such change in GAAP. Notwithstanding any terms in this Agreement to the contrary, for purposes of any financial covenant and other financial calculations in this Agreement (other than for purposes of updating the Borrowing Base) which are made in whole or in part based upon the Availability Amount as of the last day of a particular month, calculations relying on information from a Borrowing Base Statement shall be derived from the Borrowing Base Statement delivered within seven (7) days of month end pursuant to Section 5.3(a) (and not, for clarity, any more recent Borrowing Base Statement delivered after such period), and the actual delivery date of such Borrowing Base Statement shall be deemed to be the last day of the applicable month.

(b) As used in the Loan Documents: (i) the words “shall” or “will” are mandatory, the word “may” is permissive, the word “or” is not exclusive, the words “includes” and “including” are not limiting, the singular includes the plural, and numbers denoting amounts that are set off in brackets are negative; (ii) the term “continuing” in the context of an Event of Default means that the Event of Default has not been remedied (if capable of being remedied) or waived; and (iii) whenever a representation or warranty is made to Borrower’s knowledge or awareness, to the “best of” Borrower’s knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of any Responsible Officer.

12.2 Definitions. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in this Section 12.2. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. As used in this Agreement, the following capitalized terms have the following meanings:

“**Account**” is, as to any Person, any “account” of such Person as “account” is defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to such Person.

“**Account Debtor**” is any “account debtor” as defined in the Code with such additions to such term as may hereafter be made.

“**Administrator**” is an individual that is named:

(a) as an “Administrator” in the “SVB Online Services” form completed by Borrower with the authority to determine who will be authorized to use SVB Online Services (as defined in Bank’s Online Banking Agreement as in effect from time to time) on behalf of Borrower; and

(b) as an Authorized Signer of Borrower in an approval by the Board.

“**Advance**” or “**Advances**” means a revolving credit loan (or revolving credit loans) under the Revolving Line.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

"**Affiliate**" is, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members. For purposes of the definition of Eligible Accounts, Affiliate shall include a Specified Affiliate.

"**Agreement**" is defined in the preamble hereof.

"**ABPO**" means [*]. Any Advance made against the ABPO amount must be repaid within eighteen (18) months of the Funding Date thereof, [*].

[*]

"**Anti-Terrorism Law**" means any law relating to terrorism or money-laundering, including Executive Order No. 13224 and the USA Patriot Act.

"**Applicable Law**" means all applicable provisions of constitutions, laws, statutes, ordinances, rules, treaties, regulations, permits, licenses, approvals, interpretations and orders of courts or Governmental Authorities and all orders and decrees of all courts and arbitrators.

"**Authorized Signer**" means any individual listed in Borrower's Borrowing Resolution who is authorized to execute the Loan Documents, including making (and executing if applicable) any Credit Extension request, on behalf of Borrower.

"**Availability Amount**" is (i) when a Streamline Period is in effect, the Revolving Line or (ii) when a Streamline Period is not in effect, the lesser of a) the Revolving Line or (b) the Borrowing Base, minus, in either case, the outstanding principal amounts of any Advances.

"**Bank**" is defined in the preamble hereof.

"**Bank Entities**" is defined in Section 11.8.

"**Bank Expenses**" are all audit fees, reasonable and documented out of pocket costs and expenses (including reasonable, out-of-pocket and documented attorneys' fees and expenses) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to Borrower or any Guarantor.

"**Bank Services**" are any products, credit services, and/or financial accommodations previously, now, or hereafter provided to Borrower or any of its Subsidiaries by Bank or any Bank Affiliate, including, without limitation, any letters of credit, cash management services (including, without limitation, merchant services, direct deposit of payroll, business credit cards, and check cashing services), interest rate swap arrangements, and foreign exchange services as any such products or services may be identified in Bank's various agreements related thereto (each, a "**Bank Services Agreement**").

"**Bank Services Agreement**" is defined in the definition of Bank Services.

"**BARDA**" means Biomedical Advanced Research and Development Authority.

"**BARDA Procurement Contract**" means the in the original procurement agreement with BARDA to be entered into by Borrower in 2022.

"**Board**" is Borrower's board of directors or equivalent governing body.

"**Borrower**" is set forth on Schedule I hereto.

"**Borrower's Books**" are all Borrower's books and records including ledgers, federal and state tax returns, records regarding Borrower's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

"**Borrowing Base**" is (a) [*] of Eligible Accounts plus (b) [*] of ABPOs plus (c) [*] of Eligible Purchase Orders, as reasonably determined by Bank from Borrower's most recent Borrowing Base Statement (and as may subsequently be updated by Bank, in consultation with Borrower, based upon information received by Bank including, without limitation, Accounts that are paid and/or billed following the date of the Borrowing Base Statement or purchase orders that are cancelled); provided, however, that Bank has the right to decrease the foregoing percentages in its good faith business judgment, in consultation with Borrower, to mitigate the impact of events, conditions, contingencies, or risks which may materially adversely affect the Collateral or its value.

"**Borrowing Base Statement**" is that certain statement of the value of certain Collateral in the form specified by Bank to Borrower from time to time.

"**Borrowing Resolutions**" are, with respect to any Person, those resolutions adopted by such Person's board of directors (and, if required under the terms of such Person's Operating Documents, stockholders) and delivered by such Person to Bank approving the Loan Documents to which such Person is a party and the transactions contemplated thereby, together with a certificate executed by its secretary on behalf of such Person certifying (a) such Person has the authority to execute, deliver, and perform its obligations under each of the Loan Documents to which it is a party, (b) that set forth as a part of or attached as an exhibit to such certificate is a true, correct, and complete copy of the resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Person of the Loan Documents to which it is a party, (c) the name(s) of the Person(s) authorized to execute the Loan Documents, including making (and executing if applicable) any Credit Extension request, on behalf of such Person, together with a sample of the true signature(s) of such Person(s), and (d) that Bank may conclusively rely on such certificate unless and until such Person shall have delivered to Bank a further certificate canceling or amending such prior certificate.

"**Business Day**" is a day other than a Saturday, Sunday or other day on which commercial banks in the State of California are authorized or required by law to close, except that if any determination of a "Business Day" shall relate to an FX Contract, the term "Business Day" shall mean a FX Business Day.

"**Cash Burn**" is GAAP net income plus (i) depreciation, (ii) amortization, (iii) non-cash stock compensation, (iv) one-time milestone and business development payments and (v) other non-recurring, extraordinary costs and expenses outside of the ordinary course of business agreed to by Bank writing.

"**Cash Collateral Account**" is defined in Section 5.4(c).

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (c) Bank's certificates of deposit issued maturing no more than one (1) year after issue; (d) money market funds at least [*] of the assets of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) of this definition and (e) other Investments made in accordance with Borrower's written investment policy approved in writing by Bank.

"**Cayman Islands Electronic Signature Law**" is defined in Section 11.9.

"**Change in Control**" means (a) during any period of twelve (12) consecutive months, a majority of the members of the Board of Borrower cease to be composed of individuals (i) who were members of that board or equivalent governing body on the first (1st) day of such period, (ii) whose election or nomination to that board or equivalent governing body was approved by individuals referred to in clause (i) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body or (iii) whose election or nomination to that board or other equivalent governing body was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body; or (b) at any time, Borrower shall cease to own and control, of record and beneficially, directly or indirectly, one hundred percent (100.0%) of each class of outstanding stock, partnership, membership, or other ownership interest or other equity securities of each Subsidiary of Borrower free and clear of all Liens (except Permitted Liens).

"**Change in Law**" means the occurrence, after the Effective Date, of: (a) the adoption or taking effect of any law, rule, regulation or treaty; (b) any change in Applicable Law or in the administration, interpretation, implementation or application thereof by any Governmental Authority; or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that notwithstanding anything herein to the contrary, (i) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (ii) all requests, rules, guidelines or directives promulgated by Bank for International Settlements, the Basel Committee on Banking

Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"**Claims**" is defined in Section 11.3.

"**CLIN**" means, each option, as identified by a line-item number, in the BARDA Procurement Contract which relates to a potential fixed price procurement of a certain number of TEMBEXA treatment courses at a specified price.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Bank's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" consists of all of Borrower's right, title and interest in and to the following personal property:

(a) (i) all goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as provided below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, securities accounts, securities entitlements and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and (ii) all Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

(b) Notwithstanding the foregoing, the Collateral does not include any (i) Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property, (ii) any interest of Borrower as a lessee or sublessee under a real property lease or an Equipment lease if Borrower is prohibited by the terms of such lease from granting a security interest in such lease or under which such an assignment or Lien would cause a default to occur under such lease (but only to the extent that such prohibition is enforceable under all applicable laws including, without limitation, the Code); provided, however, that upon termination of such prohibition, such interest shall immediately become Collateral without any action by Borrower or Bank. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Bank's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property.

(c) Pursuant to the terms of a certain negative pledge arrangement with Bank, Borrower has agreed not to encumber any of its Intellectual Property except for Permitted Licenses without Bank's prior written consent.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Compliance Statement**" is that certain statement in the form attached hereto as Exhibit A.

"**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability of that Person for (a) any direct or indirect guaranty by such Person of any indebtedness, lease, dividend, letter of credit, credit card or other obligation of another, (b) any other obligation endorsed, co-made, discounted or sold with recourse by that Person,

or for which that Person is directly or indirectly liable; (c) any obligations for undrawn letters of credit for the account of that Person; and (d) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower maintains a Securities Account or a Commodity Account, Borrower, and Bank pursuant to which Bank obtains control (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Credit Extension**" is any Advance, Overadvance, or any other extension of credit by Bank for Borrower's benefit.

"**Currency**" is coined money and such other banknotes or other paper money as are authorized by law and circulate as a medium of exchange.

"**Default**" means any event which with notice or passage of time or both, would constitute an Event of Default.

"**Default Rate**" is defined in Section 1.8(c).

"**Deferred Revenue**" is all amounts received or invoiced in advance of performance under contracts and not yet recognized as revenue.

"**Deposit Account**" is any "**deposit account**" as defined in the Code with such additions to such term as may hereafter be made.

"**Designated Deposit Account**" is the deposit account established by Borrower with Bank for purposes of receiving Credit Extensions.

"**Division**" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, Section 17-220 of the Delaware Revised Uniform Limited Partnership Act for limited partnerships formed under Delaware law, or any analogous action taken pursuant to any other Applicable Law with respect to any corporation, limited liability company, partnership or other entity.

"**Dollars**," "**dollars**" or use of the sign "$" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"**Dollar Equivalent**" is, at any time, (a) with respect to any amount denominated in Dollars, such amount, and (b) with respect to any amount denominated in a Foreign Currency, the equivalent amount therefor in Dollars as determined by Bank at such time on the basis of the then-prevailing rate of exchange in San Francisco, California, for sales of the Foreign Currency for transfer to the country issuing such Foreign Currency.

"**Effective Date**" is set forth on Schedule I hereto.

"**Eligible Accounts**" means Accounts owing to Borrower which arise in the ordinary course of Borrower's business that meet all Borrower's representations and warranties in Section 4.3, that have been, at the option of Bank, confirmed in accordance with Section 5.4(f) of this Agreement, and are due and owing from Account Debtors deemed creditworthy by Bank in its reasonable business discretion. Bank reserves the right, at any time after the Effective Date, in its reasonable business discretion, in each instance, to either (a) adjust any of the criteria set forth

below and to establish new criteria or (b) deem any Accounts owing from a particular Account Debtor or Account Debtors to not meet the criteria to be Eligible Accounts. Unless Bank otherwise agrees in writing, Eligible Accounts shall not include:

(a) Accounts (i) for which the Account Debtor is Borrower's Affiliate, officer, employee, investor, or agent, or (ii) that are intercompany Accounts;

(b) Accounts that the Account Debtor has not paid within ninety (90) days of invoice date regardless of invoice payment period terms;

(c) Accounts with credit balances over ninety (90) days from invoice date, to the extent of such credit balances;

(d) Accounts owing from an Account Debtor if fifty percent (50.0%) or more of the Accounts owing from such Account Debtor have not been paid within ninety (90) days of invoice date;

(e) Accounts owing from an Account Debtor (i) which does not have its principal place of business in the United States or (ii) whose billing address (as set forth in the applicable invoice for such Account) is not in the United States, unless in the case of both (i) and (ii) such Accounts are otherwise approved by Bank in writing;

(f) Accounts billed from and/or payable to Borrower outside of the United States (sometimes called foreign invoiced accounts);

(g) Accounts in which Bank does not have a first priority, perfected security interest under all Applicable Law;

(h) Accounts billed and/or payable in a Currency other than Dollars;

(i) Accounts owing from an Account Debtor to the extent that Borrower is indebted or obligated in any manner to the Account Debtor (as creditor, lessor, supplier or otherwise - sometimes called "contra" accounts, accounts payable, customer deposits or credit accounts), but only to the extent of such Indebtedness or obligations;

(j) Accounts with or in respect of accruals for marketing allowances, incentive rebates, price protection, cooperative advertising and other similar marketing credits, unless otherwise approved by Bank in writing, but only to the extent of such credits;

(k) Accounts owing from an Account Debtor which is a United States government entity or any department, agency, or instrumentality thereof unless Borrower has assigned its payment rights to Bank and the assignment has been acknowledged under the Federal Assignment of Claims Act of 1940, as amended;

(l) Accounts with customer deposits and/or with respect to which Borrower has received an upfront payment, to the extent of such customer deposit and/or upfront payment;

(m) Accounts for demonstration or promotional equipment, or in which goods are consigned, or sold on a "sale guaranteed", "sale or return", "sale on approval", or other terms if Account Debtor's payment may be conditional;

(n) Accounts owing from an Account Debtor where goods or services have not yet been rendered to the Account Debtor (sometimes called memo billings or pre-billings);

(o) Accounts subject to contractual arrangements between Borrower and an Account Debtor where payments shall be scheduled or due according to completion or fulfillment requirements (sometimes called contracts accounts receivable, progress billings, milestone billings, or fulfillment contracts);

(p) Accounts owing from an Account Debtor the amount of which may be subject to withholding based on the Account Debtor's satisfaction of Borrower's complete performance (but only to the extent of the amount withheld; sometimes called retainage billings);

(q) Accounts subject to trust provisions, subrogation rights of a bonding company, or a statutory trust;

(r) Accounts owing from an Account Debtor that has been invoiced for goods that have not been shipped to the Account Debtor unless Bank, Borrower, and the Account Debtor have entered into an agreement acceptable to Bank wherein the Account Debtor acknowledges that (i) it has title to and has ownership of the goods wherever located, (ii) a bona fide sale of the goods has occurred, and (iii) it owes payment for such goods in accordance with invoices from Borrower (sometimes called "bill and hold" accounts);

(s) Accounts for which the Account Debtor has not been invoiced;

(t) Accounts that represent non-trade receivables or that are derived by means other than in the ordinary course of Borrower's business;

(u) Accounts for which Borrower has permitted Account Debtor's payment to extend beyond ninety (90) days (including Accounts with a due date that is more than ninety (90) days from invoice date);

(v) Accounts arising from chargebacks, debit memos or other payment deductions taken by an Account Debtor;

(w) Accounts arising from product returns and/or exchanges (sometimes called "warranty" or "RMA" accounts);

(x) Accounts in which the Account Debtor disputes liability or makes any claim (but only up to the disputed or claimed amount), or if the Account Debtor is subject to an Insolvency Proceeding (whether voluntary or involuntary), or becomes insolvent, or goes out of business;

(y) Accounts owing from an Account Debtor with respect to which Borrower has received Deferred Revenue (but only to the extent of such Deferred Revenue);

(z) Accounts owing from an Account Debtor, whose total obligations to Borrower exceed twenty-five percent (25.0%) of all Accounts (but only to the extent that the amount due exceeds the concentration limit), except for Accounts owing from BARDA, which are not subject to this concentration limit; and

(aa) Accounts for which Bank in its sole discretion determines collection to be doubtful, including, without limitation, accounts represented by "refreshed" or "recycled" invoices.

"**Eligible Purchase Orders**" are Purchase Orders for the sale of Borrower's non-TEMBEXA goods, in form and substance acceptable to Bank in its reasonable business discretion, (i) that are executed by a customer of Borrower having its principal place of business located in the United States which is not a United States government entity or any department, agency, or instrumentality thereof, and (ii) for which the shipping date is not more than ninety (90) days after the invoice date associated with such purchase order and specifically excludes ABPOs.

"**Environmental Laws**" means any Applicable Law (including any permits, concessions, grants, franchises, licenses, agreements or governmental restrictions) relating to pollution or the protection of health, safety or the environment or the release of any materials into the environment (including those related to hazardous materials, air emissions, discharges to waste or public systems and health and safety matters).

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"**Event of Default**" is defined in Section 7.

"**Exchange Act**" is the Securities Exchange Act of 1934, as amended.

"**Excluded Taxes**" means any of the following Taxes imposed on or with respect to Bank or required to be withheld or deducted from a payment to Bank, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Bank being

organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Bank with respect to an applicable interest in a Credit Extension or the Revolving Line pursuant to a law in effect on the date on which (i) Bank acquires such interest in the Credit Extensions or Revolving Line or (ii) Bank changes its lending office, except in each case to the extent that, pursuant to Section 1.12, amounts with respect to such Taxes were payable either to Bank's assignor immediately before Bank became a party hereto or to Bank immediately before it changed its lending office, (c) Taxes attributable to Bank's failure to comply with Section 1.12(e), and (d) any withholding Taxes imposed under FATCA.

"**FATCA**" means Sections 1471 through 1474 of the Internal Revenue Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Internal Revenue Code.

"**Financial Statement Repository**" is MASE@svb.com or such other means of collecting information approved and designated by Bank after providing notice thereof to Borrower from time to time.

"**Foreign Currency**" is the lawful money of a country other than the United States.

"**Funding Date**" is any date on which a Credit Extension is made to or for the account of Borrower which shall be a Business Day.

"**FX Business Day**" is any day when (a) Bank's Foreign Exchange Department is conducting its normal business and (b) the Foreign Currency being purchased or sold by Borrower is available to Bank from the entity from which Bank shall buy or sell such Foreign Currency.

"**FX Contract**" is any foreign exchange contract by and between Borrower and Bank under which Borrower commits to purchase from or sell to Bank a specific amount of Foreign Currency at a set price or on a specified date (the "**Settlement Date**").

"**FX Reduction Amount**" means, with respect to a given FX Contract, the notional amount thereof multiplied by the currency exchange risk factor for the currencies involved in the FX Contract, multiplied by the current foreign exchange spot rates, in each instance as determined and calculated by Bank in its sole discretion.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" is all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all Intellectual Property, claims, income and other tax refunds, security and other deposits, payment intangibles, contract rights, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Guarantor**" is any Person providing a Guaranty in favor of Bank.

"**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations (other than real property operating leases), (d) Contingent Obligations and (e) other short- and long-term obligations under debt agreements, lines of credit and extensions of credit. Indebtedness shall not include any milestone payments made by Borrower or its Subsidiaries.

"**Indemnified Person**" is defined in Section 11.3.

"**Indemnified Taxes**" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (b) to the extent not otherwise described in clause (a), Other Taxes.

"**Information**" is defined in Section 11.8.

"**Initial Audit**" is Bank's inspection of Borrower's Accounts, the Collateral, and Borrower's Books, with results satisfactory to Bank in its reasonable business discretion.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, receivership or other relief.

"**Intellectual Property**" means, with respect to any Person, all of such Person's right, title, and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how and operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to such Person;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Internal Revenue Code**" means the U.S. Internal Revenue Code of 1986, and the rules and regulations promulgated thereunder, each as amended or modified from time to time.

"**Inventory**" is all "**inventory**" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of Borrower's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership, membership, or other ownership interest or other equity securities), and any loan, advance or capital contribution to any Person.

"**Judgment Currency**" is defined in Section 11.3.

"**Key Person**" is Borrower's CEO.

"**Lien**" is a claim, mortgage, deed of trust, levy, attachment charge, pledge, hypothecation, security interest or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Liquidity**" is the aggregate amount of unrestricted and unencumbered cash and Cash Equivalents held at such time by Borrower in Deposit Accounts or Securities Accounts maintained with Bank or its Affiliates or subject to a Control Agreement.

"**Loan Documents**" are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Perfection Certificate, Control Agreements, any Bank Services Agreement, any subordination agreement, any note, or notes or guaranties executed by Borrower or any Guarantor, landlord waivers and consents, bailee waivers and consents, and any other present or future agreement by Borrower and/or any Guarantor with or for the benefit of Bank in connection with this Agreement or Bank Services, all as amended, restated, or otherwise modified in accordance with the terms thereof.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Bank's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations, or condition (financial or otherwise) of Borrower; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"**Obligations**" are Borrower's obligations to pay when due any debts, principal, interest, fees, Bank Expenses, the Termination Fee, the Commitment Fee, the Unused Revolving Line Facility Fee, and other amounts Borrower owes Bank now or later, whether under this Agreement, the other Loan Documents, or otherwise, including, without limitation, all obligations relating to Bank Services and interest accruing after Insolvency Proceedings begin and debts, liabilities, or obligations of Borrower assigned to Bank, and to perform Borrower's duties under the Loan Documents.

"**OFAC**" is the Office of Foreign Assets Control of the United States Department of the Treasury and any successor thereto.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership or limited partnership, its partnership agreement or limited partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Other Connection Taxes**" means, with respect to Bank, Taxes imposed as a result of a present or former connection between Bank and the jurisdiction imposing such Tax (other than connections arising from Bank having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Credit Extension or Loan Document).

"**Other Taxes**" means all present or future stamp, court, documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

"**Overadvance**" is defined in Section 1.7.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"**Payment/Advance Form**" is that certain form in the form attached hereto as Exhibit B.

"**Payment Date**" is set forth on Schedule I hereto.

"**Perfection Certificate**" is the Perfection Certificate delivered by Borrower in connection with this Agreement.

"**Permitted Acquisition**" or "**Permitted Acquisitions**" means the purchase or other acquisition (whether by merger, consolidation, or otherwise) by Borrower or all or substantially all of the assets, stock, or other equity interests of a Person, provided that each of the following shall be applicable to each such acquisition:

(a) no Event of Default shall have occurred and be continuing or would result from the consummation of the proposed acquisition and Bank has received evidence that Borrower is in compliance with all terms and conditions of this Agreement on a *pro forma* basis after giving effect to such acquisition;

(b) the entity or assets acquired in such acquisition are in the same or similar line of business as Borrower is in as of the Effective Date or reasonably related, incidental or ancillary thereto;

(c) if the acquisition includes a merger of Borrower, Borrower shall remain the surviving legal entity after giving effect to such acquisition;

(d) if, as a result of such acquisition, a new Subsidiary of Borrower is formed or acquired, Borrower shall cause such Subsidiary to comply with the terms of Section 5.14 of this Agreement;

(e) Borrower shall provide Bank with written notice of the proposed acquisition at least five (5) days prior to the anticipated closing date of the proposed acquisition;

(f) the total cash consideration does not exceed (i) Forty Million Dollars ($40,000,000) in the aggregate for any consideration paid upfront or based upon clinical milestones or (ii) an unlimited amount based on approval or sales milestones;

(g) the acquisition has been approved by (i) the Board and (ii) the board of directors (or other legally governing body) of the Person to be acquired; and

(h) no Indebtedness will be incurred, assumed, or would exist with respect to Borrower or its Subsidiaries as a result of the contemplated transaction, other than Permitted Indebtedness.

"**Permitted Convertible Debt**" means any unsecured notes issued by the Borrower that are or will become convertible into or exchangeable for a fixed number (subject to customary anti-dilution adjustments, "make-whole" increases and other customary changes thereto) of shares of common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower) (and cash in lieu of fraction shares), cash or any combination thereof (with the amount of such shares, cash or such combination determined by reference to the market price of such common stock or such other securities); *provided* that such Indebtedness must satisfy each of the following conditions: (i) both immediately prior to and after giving effect (including pro forma effect) to the issuance thereof, no Default or Event of Default shall exist or result therefrom, (ii) such Indebtedness matures after, and does not require any scheduled amortization or other scheduled or otherwise required payments of principal prior to, or have a scheduled maturity date earlier than, the date that is ninety one (91) calendar days after the Revolving Line Maturity Date and prior to that date, does not provide for or require any payments of principal or any other payments with the exception of semi-annual interest payments, obligations to settle conversions, redemption rights and customary obligations to offer to repurchase the notes upon the occurrence of a "fundamental change", (iii) any cross-default or cross-acceleration event of default (each howsoever defined) provision contained therein that relates to indebtedness or other payment obligations of Borrower (or any of its Subsidiaries) (such indebtedness or other payment obligations, a "**Cross-Default Reference Obligation**") contains a cure period of at least thirty (30) calendar days (after written notice to the issuer of such Indebtedness by the trustee or to such issuer and such trustee by holders of at least [*] in aggregate principal amount of such Indebtedness then outstanding) before a default, event of default, acceleration or other event or condition under such Cross-Default Reference Obligation results in an event of default under such cross-default or cross-acceleration provision (iv) the terms, conditions and covenants (other than pricing terms determined through a customary marketing process) of such Indebtedness must be customary for convertible Indebtedness of such type at the time of issuance (as determined by the Board, or a committee thereof, in good faith), and (vi) such Indebtedness is not guaranteed by any Subsidiary of the Borrower unless the Obligations are guaranteed by such Subsidiary on a secured basis. For the avoidance of doubt, and without limitation of the foregoing, for purposes of this Agreement, Permitted Convertible Debt shall at all times be valued at the full stated principle amount thereof and shall not include any reduction or appreciation in value of the shares deliverable upon conversion thereof.

"**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to Bank under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date which is shown on the Perfection Certificate;

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(f) Indebtedness secured by Liens permitted under clauses (a) and (c) of the definition of "Permitted Liens" hereunder;

(g) Permitted Convertible Debt in aggregate principal amount not to exceed Fifty Million Dollars ($50,000,000) in principal amount at any time outstanding

(h) Unsecured Indebtedness incurred in connection with Borrower's AMEX program in an aggregate principal amount equal to [*];

(i) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business;

(j) Other unsecured Indebtedness in an aggregate principal amount not to exceed [*] at any time outstanding;

(k) to the extent constituting Indebtedness, Permitted Investments;

(l) Indebtedness in the form of purchase price adjustments, earn-outs, approval milestones, sales milestones, royalties on future sales, deferred compensation, or other arrangements representing acquisition consideration or deferred payments of similar nature incurred in connection with any Permitted Acquisition or other investment permitted hereunder including earnout obligations existing on the Effective Date and owing to the former shareholders of Oncoceutics, Inc.;

(m) Letters of credit not with Bank in an aggregate principal amount not to exceed [*] at any time outstanding incurred by foreign Subsidiaries but only if Bank cannot issue letters of credit in the applicable foreign jurisdiction; and

(n) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (o) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"**Permitted Investments**" are:

(a) Investments (including, without limitation, Subsidiaries) existing on the Effective Date which are shown on the Perfection Certificate;

(b) Investments consisting of Cash Equivalents;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower's business;

(d) Investments consisting of deposit accounts (but only to the extent that Borrower is permitted to maintain such accounts pursuant to Section 5.9 of this Agreement) in which Bank has a first priority perfected security interest (to the extent required by Section 5.7 of this Agreement);

(e) Investments accepted in connection with Transfers permitted by Section 6.1;

(f) Investments consisting of the creation of a Subsidiary for the purpose of consummating a merger transaction permitted by Section 6.3 of this Agreement, which is otherwise a Permitted Investment;

(g) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers, directors, partners, managers and members relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee equity purchase plans or similar agreements approved by the Board;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (i) shall not apply to Investments of Borrower in any Subsidiary;

(j) Investments (i) by Borrower in a Guarantor, by Guarantors in other Guarantors or by a Guarantor in the Borrower, (ii) by Borrower in Subsidiaries that are not Guarantors not to exceed [*] in the aggregate in any fiscal year, and (iii) by Subsidiaries in other Subsidiaries that are not Guarantors;

(k) other Investments not otherwise permitted hereunder in an amount not to exceed [*] in the aggregate per year;

(l) Permitted Acquisitions;

(m) investments of any Person existing at the time such Person becomes a Subsidiary of a Borrower or consolidates or merges with a Borrower or any of such party's Subsidiary (including in connection with a Permitted Acquisition), so long as such investments were not made in contemplation of such Person becoming a Subsidiary or of such merger.

"**Permitted Licenses**" means (i) non-exclusive licenses for the use of the property of Borrower or its Subsidiaries in the ordinary course of business and licenses that could not result in a legal transfer of title of the licensed property but that may be exclusive in respects other than territory and that may be exclusive as to territory only as to discreet geographical areas outside of the United States, (ii) the Borrower's existing licenses listed on the Perfection Certificate, (iii) licenses granted in connection with development agreements and clinical trials and other non-commercial programs and (iv) licenses of Borrower's intellectual property to products other than those related to [*].

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date which are shown on the Perfection Certificate or arising under this Agreement or the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on Borrower's Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code;

(c) purchase money Liens (i) on Equipment acquired or held by Borrower incurred for financing the acquisition of the Equipment securing no more than [*] in the aggregate amount outstanding, or (ii) existing on Equipment when acquired, if the Lien is confined to the property and improvements and the proceeds of the Equipment;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed [*] and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the Indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Bank a security interest therein;

(h) Permitted Licenses;

(i) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under Sections 7.4 and 7.7;

(j) Liens on insurance proceeds granted solely as a security for financed premiums to the extent the Indebtedness secured thereby is permitted under clause (i) of Permitted Indebtedness;

(k) Liens in the form of deposits for real property leases and Liens securing letters of credit permitted under clause (o) of the definition of Permitted Indebtedness;

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prime Rate**" is set forth on Schedule I hereto.

"**Prime Rate Margin**" is set forth on Schedule I hereto.

"**Purchase Order**" is a purchase order for Borrower's goods.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"**Representatives**" is defined in Section 11.8.

"**Reserves**" means, as of any date of determination, such amounts as Bank may from time to time establish and revise in its reasonable business discretion, reducing the amount of Advances and other financial accommodations which would otherwise be available to Borrower (a) to reflect events, conditions, contingencies or risks which, as determined by Bank in its sole discretion, do or may adversely affect (i) the Collateral or any other property which is security for the Obligations or its value (including without limitation any increase in delinquencies of Accounts), (ii) the assets, business or prospects of Borrower or any Guarantor, or (iii) the security interests and other rights of Bank in the Collateral (including the enforceability, perfection and priority thereof); or (b) to reflect Bank's reasonable belief that any collateral report or financial information furnished by or on behalf of Borrower or any Guarantor to Bank is or may have been incomplete, inaccurate or misleading in any material respect; or (c) in respect of any state of facts which Bank determines in its reasonable business discretion constitutes a Default or an Event of Default.

"**Responsible Officer**" is any of the Chief Financial Officer or Executive Director of Finance & Accounting of Borrower.

"**Restricted License**" is any material license or other material agreement with respect to which Borrower is the licensee (a) that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such license or agreement or any other property, or (b) for which a default under or termination of could reasonably be expected to interfere with Bank's right to sell any Collateral.

"**Revolving Line**" is set forth on Schedule I hereto.

"**Revolving Line Maturity Date**" is set forth on Schedule I hereto.

"**Sanctioned Person**" means a Person that: (a) is listed on any Sanctions list maintained by OFAC or any similar Sanctions list maintained by any other Governmental Authority having jurisdiction over Borrower; (b) is located, organized, or resident in any country, territory, or region that is the subject or target of Sanctions; or (c) is fifty percent (50.0%) or more owned or controlled by one (1) or more Persons described in clauses (a) and (b) hereof.

"**Sanctions**" means the economic sanctions laws, regulations, embargoes or restrictive measures administered, enacted or enforced by the United States government and any of its agencies, including, without limitation, OFAC and the U.S. State Department, or any other Governmental Authority having jurisdiction over Borrower.

"**SEC**" is the Securities and Exchange Commission, any successor thereto, and any analogous Governmental Authority.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Settlement Date**" is defined in the definition of FX Contract.

"**Specified Affiliate**" is any Person (a) more than [*] of whose aggregate issued and outstanding equity or ownership securities or interests, voting, non-voting or both, are owned or held directly or indirectly, beneficially or of record, by Borrower, and/or (b) whose equity or ownership securities or interests representing more than [*] of such Person's total outstanding combined voting power are owned or held directly or indirectly, beneficially or of record, by Borrower.

"**Streamline Balance**" is defined in the definition of Streamline Period.

"**Streamline Period**" is, on and after the Effective Date, provided no Event of Default has occurred and is continuing, the period (a) commencing on the first (1st) day of the month following the day that Borrower provides to Bank a written report that Borrower has, for each consecutive day in the immediately preceding month maintained unrestricted cash in an amount that is at all times equal to or greater than either (i) [*] the maximum outstanding balance under the Revolving Line during such month or (ii) the maximum outstanding balance under the Revolving Line during such month plus trailing [*] Cash Burn, as determined by Bank in its reasonable business discretion, (the "**Streamline Balance**"); and (b) terminating on the earlier to occur of (i) the occurrence and continuance of an Event of Default that has not been waived in writing by Bank, and (ii) the first (1st) day thereafter in which Borrower fails to maintain the Streamline Balance, as determined by Bank in its reasonable business discretion. Upon the termination of a Streamline Period, Borrower shall maintain the Streamline Balance each consecutive day for a full calendar month, prior to entering into a subsequent Streamline Period. The Streamline Period shall commence on the first (1st) day of the monthly period following the date Bank determines, in its reasonable business discretion, that the Streamline Balance has been achieved.

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all of Borrower's or any of its Subsidiaries' now or hereafter indebtedness to Bank (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Bank entered into between Bank and the other creditor), on terms reasonably acceptable to Bank.

"**Subsidiary**" is, as to any Person, a corporation, partnership, limited liability company or other entity of which shares of stock, partnership, membership, or other ownership interest or other equity securities having ordinary voting power (other than stock, partnership, membership, or other ownership interest or other equity securities having such power only by reason of the happening of a contingency) to elect a majority of the board of directors or other managers of such corporation, partnership or other entity are at the time owned, or the management of which is otherwise controlled, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of Borrower.

"**Taxes**" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Trademarks**" means, with respect to any Person, any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of such Person connected with and symbolized by such trademarks.

"**Transfer**" is defined in Section 6.1.

"**Unused Revolving Line Facility Fee**" is defined in Section 1.9(d).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

"**USA Patriot Act**" means the "Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001" (Public Law 107-56, signed into law on October 26, 2001), as amended from time to time.

[Signature page follows]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

CHIMERIX, INC.

By: /s/ Mike Andriole

Name: Mike Andriole

Title: Chief Business Officer and CFO

BANK:

SILICON VALLEY BANK

By: /s/ Michael McMahon

Name: Michael McMahon

Title: Director

SCHEDULE I

LSA PROVISIONS

LSA Section	**LSA Provision**
1.1(a) – Revolving Line – Availability	Amounts borrowed under the Revolving Line may be prepaid or repaid and, prior to the Revolving Line Maturity Date, reborrowed, subject to the applicable terms and conditions precedent herein.
1.8(a)(i) – Interest Payments – Advances	Interest on the principal amount of each Advance is payable in arrears monthly (i) on each Payment Date, (ii) on the date of any prepayment and (iii) on the Revolving Line Maturity Date.
1.8(a)(i)– Interest Rate – Advances	The outstanding principal amount of any Advance shall accrue interest at a floating rate per annum equal to the greater of (A) four and three quarters percent (4.75%) and (B) the Prime Rate plus the Prime Rate Margin, which interest shall be payable in accordance with Section 1.8(a).
1.8(f)– Interest Computation	Interest shall be computed on the basis of the actual number of days elapsed.
1.9(a) – Revolving Line Commitment Fee	A fully earned, non-refundable commitment fee of Five Hundred Thousand Dollars ($500,000), payable in installments of [*] beginning on the Effective Date and at each one-year anniversary; provided however upon the acceleration of the Advances after the occurrence of an Event of Default or termination of this Agreement prior to the Revolving Line Maturity Date, any balance owing with respect to such fee shall immediately become due and payable.
12.2– "Borrower"	"**Borrower**" means CHIMERIX, INC., a Delaware corporation.
12.2– "Effective Date"	"**Effective Date**" is January 31, 2022.
12.2– "Payment Date"	"**Payment Date**" is with respect to Advances, the last calendar day of each month.
12.2– "Prime Rate"	"**Prime Rate**" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of California (such Bank announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than zero percent (0.0%) per annum, such rate shall be deemed to be zero percent (0.0%) per annum for purposes of this Agreement.

12.2– "Prime Rate Margin"	"**Prime Rate Margin**" is one and one-half percent (1.50%).
12.2– "Revolving Line"	"**Revolving Line**" is an aggregate principal amount equal to Fifty Million Dollars ($50,000,000).
12.2 – "Revolving Line Maturity Date"	"**Revolving Line Maturity Date**" is January 31, 2026.

EXHIBIT A

COMPLIANCE STATEMENT

TO: SILICON VALLEY BANK Date: ____
FROM: CHIMERIX, INC.

Under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (as amended, modified, supplemented and/or restated from time to time, the "**Agreement**"), Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below. Attached are the required documents evidencing such compliance, setting forth calculations prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	Required	Complies
Monthly financial statements with Compliance Statement	Monthly within 30 days	Yes No
Annual financial statements (CPA Audited)	FYE within 90 days	Yes No
Quarterly SEC filings	Within 45 days of quarter end (except Q4/FYE – due within 90 days)	Yes No
10-Q, 10-K and 8-K	Within 5 days after filing with SEC	Yes No
A/R & A/P Agings*	Monthly within 30 days	Yes No
Borrowing Base Statements*	Monthly within 30 days	Yes No
Board approved projections	FYE within 30 days and as amended/updated	Yes No
UBS Account Statements	Upon demand by Bank	Yes No
**Only due when there is an outstanding balance under the Revolving Line and a Streamline Period is not in effect*		

Financial Covenant	Required	Actual	Complies
Liquidity	See Section 5.10 of the Loan Agreement	$	Yes No
Min cash at Bank	See Section 5.10 of the Loan Agreement	$	Yes No

The following financial covenant analyses and information set forth in Schedule 1 attached hereto are true and correct as of the date of this Compliance Statement.

The following are the exceptions with respect to the statements above: (If no exceptions exist, state "No exceptions to note.")

EXHIBIT B

LOAN PAYMENT/ADVANCE REQUEST FORM

Deadline for same day processing is Noon Eastern Time

fax to: Date: _____

Loan Payment:

CHIMERIX, INC.

From Account #_____ To Account _____
(Deposit Account #) (Loan Account #)

Principal $_____ and/or Interest $_____

Authorized Signature:__ Phone Number: __
Print Name/Title: __

Loan Advance:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account #_____ To Account #_____
(Loan Account #) (Deposit Account #)

Amount of Term Loan Advance $_____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date:

Authorized Signature:__ Phone Number: __

Print Name/Title: __

outgoing wire request:

Complete only if all or a portion of funds from the loan advance above is to be wired.
Deadline for same day processing is noon, Eastern Time

Beneficiary Name: _____ Amount of Wire: $__
Beneficiary Bank: _____ Account Number: __
City and State: __

Beneficiary Bank Transit (ABA) #: __ Beneficiary Bank Code (Swift, Sort, Chip, etc.): __
(For International Wire Only)

Intermediary Bank: __ Transit (ABA) #: __
For Further Credit to: __

Special Instruction: __

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature:__ 2nd Signature (if required):__
Print Name/Title:__ Print Name/Title:__
Telephone #:__ Telephone #:__

Exhibit 21.1

Subsidiaries of Chimerix, Inc.

Oncoceutics, Inc., a Delaware corporation

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-187860) pertaining to the 2002 Equity Incentive Plan, 2012 Equity Incentive Plan, 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of Chimerix, Inc.,
2. Registration Statement (Form S-8 Nos. 333-194408, 333-202582, 333-209802, 333-216396, 333-223344, 333-230071, 333-233115, 333-236610, and 333-253494) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of Chimerix, Inc., and
3. Registration Statement (Form S-3 No. 333-244146 and 333-255810) of Chimerix, Inc.;

of our reports dated March 1, 2022 with respect to the consolidated financial statements of Chimerix, Inc. and the effectiveness of internal control over financial reporting of Chimerix, Inc. included in this Annual Report (Form 10-K) of Chimerix, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Raleigh, North Carolina
March 1, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael A. Sherman, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of Chimerix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

/s/ Michael A. Sherman
Michael A. Sherman
President & Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael T. Andriole, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of Chimerix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

/s/ Michael T. Andriole

Michael T. Andriole
Chief Business and Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Chimerix, Inc. (the "Company") for the period ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Sherman, as Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2022

/s/ Michael A. Sherman
Michael A. Sherman
President & Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Chimerix, Inc. (the "Company") for the period ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael T. Andriole, as Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2022

/s/ Michael T. Andriole
Michael T. Andriole
Chief Business and Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

DESCRIPTION OF COMMON STOCK

The following summary description of the common stock of Chimerix, Inc. (we, our or us) is based on the provisions of our amended and restated certificate of incorporation, as well as our amended and restated bylaws, and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our amended and restated certificate of incorporation, amended and restated bylaws, and the Delaware General Corporation Law. Our amended and restated certificate of incorporation and amended and restated bylaws have previously been filed as exhibits with the Securities and Exchange Commission.

Common Stock

Voting Rights

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights.

Dividends and Other Distributions

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Distribution on Dissolution

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulting in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the commencement of the transaction, excluding for purposes of determining the number of shares outstanding (but not the outstanding voting stock owned by the interested stockholder) (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in

writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exists any vacancies); and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (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 directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine (these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction).

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock.

Listing

Our common stock is listed on The Nasdaq Global Market under the trading symbol "CMRX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is P.O. Box 43078, Providence, Rhode Island 02940.