UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31 , 2023

or

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

For the transition period from to

Commission file number: 001-35867

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 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. o

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

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

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, 2023 was $ 93,625,587 .

The number of outstanding shares of the registrant’s common stock, par value $0.001 per share, as of February 23, 2024 was 89,210,356 .

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, 2023 are incorporated by reference into Part III of this report……	III

CHIMERIX, INC.
FORM 10-K
For the Fiscal Year Ended December 31, 2023
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," "would," "could," "expect," "anticipate," "intend," "plan," "believe," "estimate," "project" 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, requirements, including the need to develop a companion diagnostic, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our ability to leverage external capital to develop our early-stage pipeline of product candidates;
- the election of the U.S. government to exercise future procurement options for TEMBEXA®;
- the potential for royalty and milestone revenue from our strategic collaborations;
- 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;
- our ability to enter into transactions to build our product candidate pipeline; 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 anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- All of our 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 our clinical candidates, including our most advanced clinical candidate, ONC201.
- 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.

- Following regulatory approval for any of our product candidates, including ONC201, 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 and clinical drug supplies, and intend to rely on third parties to produce commercial supplies of any approved product candidates.
- 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.
- The anticipated benefits of the sale of our TEMBEXA assets to Emergent Biodefense Operations Lansing LLC, (Emergent) may not be realized fully or at all or may take longer to realize than expected.
- Our ability to receive future contingent consideration from the sale depends on, among other things, Emergent's ability to successfully develop and commercialize TEMBEXA.
- 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.
- Increasing demand for compassionate use or third-party supply of our unapproved therapies could impair or delay the completion of our controlled clinical trials or otherwise result in losses.
- 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.

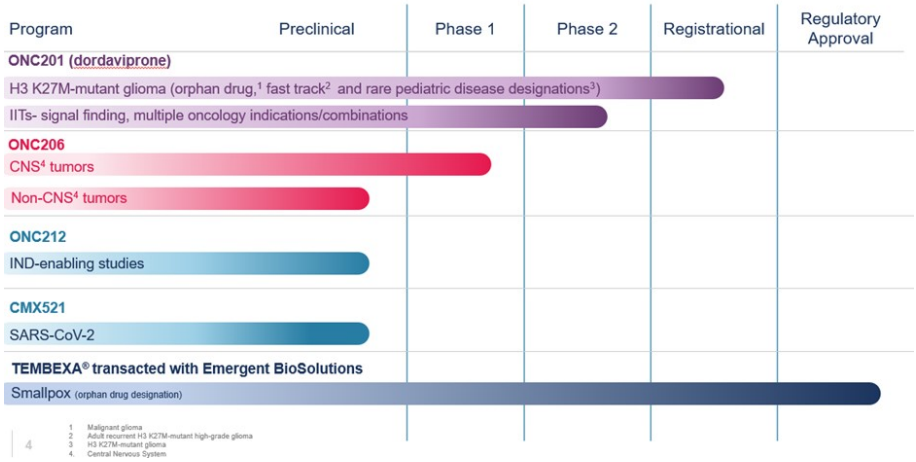
Market, Industry and Other Data

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 (Chimerix, we, our, us or the Company) is a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. The Company is focused on developing imipridones as a potential new class of selective cancer therapies. The most advanced imipridone is dordaviprone (ONC201) which is in clinical-stage development for H3 K27M-mutant diffuse glioma as its lead indication. In addition, a second-generation imipridone (ONC206) is currently in dose escalating clinical trials for adult and pediatric patients with primary central nervous system tumors.



Imipridones and ONC201 (dordaviprone)

Imipridones are a potential new class of selective cancer therapies. These drug candidates bind specifically with G protein-coupled receptors (GPCRs) and mitochondrial caseinolytic protease P (ClpP), which may result in 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 other diseases.

ONC201 (International Nonproprietary Name (INN): dordaviprone) binds with specificity to 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.

ONC201 Development Program

ONC201 is currently in a global randomized Phase 3 trial (the ACTION Study) for patients with diffuse glioma, or diffuse midline glioma (DMG), which harbor a H3 K27M mutation. Frontline radiotherapy is the standard of care for these patients. DMGs that harbor the H3 K27M mutation are considered Grade IV by the World Health Organization. This patient population has few treatment options and poor prognoses.

Phase 3 ACTION Study of ONC201

The ACTION Study is currently enrolling patients at over 130 sites in 13 countries in North America, Europe, the UK, Israel, Australia and Asia. The ACTION trial enrolls patients shortly after they have completed front-line radiation therapy that is the standard of care for glioma. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Participants are randomized to receive either: (i) 625mg of ONC201 once per week (the Phase 2 dosing regimen), (ii) 625mg twice per week on two consecutive days or (iii) placebo. The study is open to pediatric and adult patients >10kg body weight and the dose will be scaled by body weight for patients weighing less than 52.5kg. Primary endpoints include Overall Survival (OS) and progression free survival (PFS). OS will be assessed for efficacy at three alpha-allocated timepoints consisting of two interim assessments by an Independent Data Monitoring Committee (IDMC) at 164 events and 246 events, respectively, and a final assessment at 327 events. The final PFS analysis will be performed after 286 events, with progression assessed using response assessment in neuro-oncology-high grade glioma (RANO HGG) and response assessment in neuro-oncology-low grade glioma (RANO-LGG) criteria by blinded independent central review (BICR). Secondary endpoints include corticosteroid response, performance status response, change from baseline in quality of life (QoL) assessments and change from baseline in neurologic function as assessed by the Neurologic Assessment in Neuro-Oncology (NANO) scale.

Future Regulatory Interactions

Our plan is to initiate a submission to regulators for approval upon a positive overall survival analysis at either of the interim or the final overall survival analyses. In addition, in the event the result of the progression free survival analysis is positive, we would discuss the potential for submission and approval of ONC201 with the regulatory authorities based on this data.

Significant Peer Reviewed Journal Publications

In August 2023, data in support of ONC201 as a treatment for H3 K27M-mutant diffuse midline gliomas (H3K27M-DMG) appeared in the peer-reviewed journal, Cancer Discovery, a journal of the American Association for Cancer Research. The manuscript titled, "Clinical efficacy of ONC201 in H3K27M-mutant diffuse midline gliomas is driven by disruption of integrated metabolic and epigenetic pathways," reported survival analyses of 71 patients with H3K27M-DMG treated with ONC201, which demonstrated promising results in a patient population with a poor prognosis and few treatment options. In addition to assessing clinical outcomes, the study corroborated mechanistic findings from laboratory models in samples from treated patients that demonstrated the ability of ONC201 to disrupt metabolic pathways and reverse a molecular signature of the H3 K27M mutation in patient's tumor samples. According to the survival analyses in this study, ONC201 frontline treatment, administered post radiation therapy, demonstrated a significant increase in median overall survival (mOS) from diagnosis in ONC201-treated versus in historical controls (21.7 months mOS vs. 12 months mOS, p<0.0001). The study was led by a team of researchers from the University of Michigan and other collaborators including several authors from Chimerix. The journal can be accessed at https://aacrjournals.org/cancerdiscovery/article/13/11/2370/729854/Clinical-Efficacy-of-ONC201-in-H3K27M-Mutant.

In February 2024, "ONC201 (dordaviprone) in Recurrent H3 K27M-mutant Diffuse Midline Glioma," was published in the Journal of Clinical Oncology (JCO), a peer reviewed journal of the American Society of Clinical Oncology (ASCO). The manuscript reports in detail the results of 50 patients with recurrent H3 K27M-DMG treated with monotherapy ONC201 who were evaluable for objective response by Response Assessment in Neuro-Oncology (RANO) high grade glioma (HGG) criteria. ONC201 demonstrated a median overall survival (mOS) of 13.7 months (95% CI: 8.0-20.3), with an overall two-year rate of survival of 35% (95% CI: 21-49) from the start of ONC201 treatment post-recurrence. The Company previously conducted a natural disease history study (n=43) in the recurrent setting evaluating patients who did not receive ONC201 which showed a mOS of 5.1 months (95% CI: 3.9-7.1) with an overall two-year survival rate of 11% (95% CI: 3.3-24.2). The top-line data from this JCO publication were previously disclosed by the Company. The journal can be accessed at https://ascopubs.org/doi/10.1200/jco.23.01134.

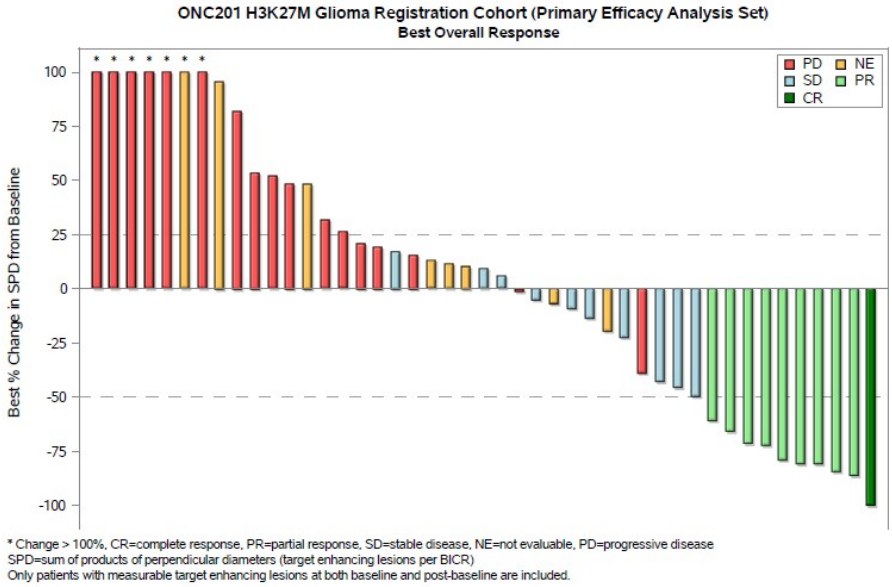
2021 Blinded Independent Central Review (BICR) of ONC201 Patient Data (JCO 2024 Publication Data)

The ONC201 Phase 2 Efficacy Analysis performed in 2021 by BICR in recurrent H3 K27M-mutant DMG demonstrated a 30% best overall response rate by Response Assessment in Neuro-Oncology criteria for high grade glioma (RANO-HGG) and/or low-grade glioma (RANO-LGG). The cohort was comprised of the first 50 patients enrolled across five ONC201 clinical protocols, who met specific criteria designed to isolate the tumor response from ONC201 monotherapy, based on feedback from the U.S. 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 radiation completed at least 90 days prior to enrollment. This data was based on strict criteria to ensure responses were attributable to a single agent. Each response required imaging and clinical criteria and was subject to a dual reader BICR.

RANO-HGG

As shown in the following waterfall plot, the RANO-HGG response assessment criteria that quantitatively evaluates neuroimaging with contrast enhancement assessed by dual reader BICR with adjudication determined:

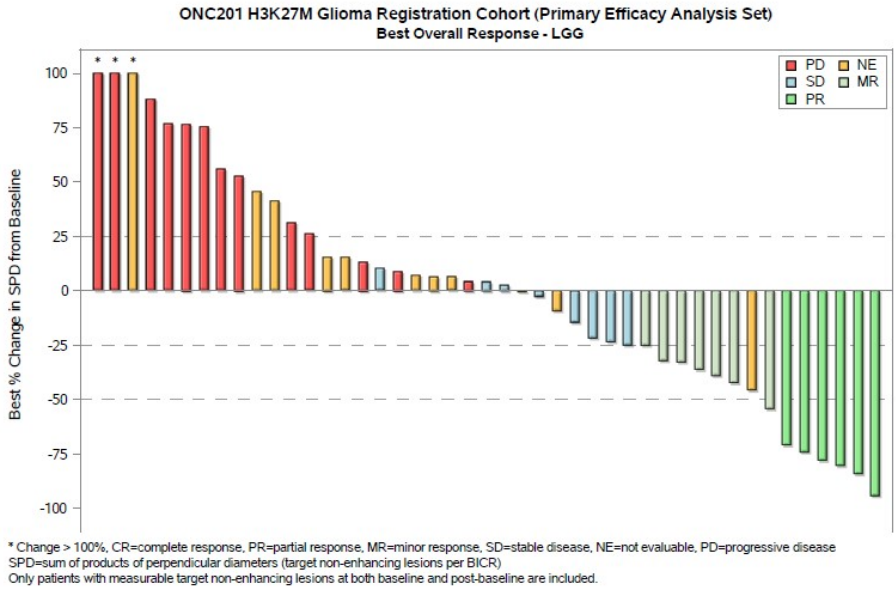
- Overall response rate (ORR) to be 20.0% (95% Confidence Interval (CI): 10.0 - 34%); including one complete response
- Disease control rate to be 40% (95% CI: 26 - 55%)



RANO-LGG

As shown in the following waterfall plot, the RANO-LGG response assessment criteria that quantitatively evaluates neuroimaging without contrast enhancement assessed by dual reader BICR with adjudication determined:

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



The proportion of patients achieving either a RANO-HGG or a RANO-LGG response, or both responses, was 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%)

Serious adverse events

To date, two serious adverse events have been reported that were considered to be possibly ONC201-related by the investigator, but were deemed unlikely to be ONC201-related by the sponsor. 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.

Natural Disease History Study

The Company sponsored a Natural Disease History study that gathered data from eleven sites in patients who did not receive ONC201. The findings of this study first reported in December 2022 support the expectation of a poor prognosis among recurrent H3 K27M-mutant diffuse glioma patients. The analysis was divided into two separate cohorts.

- *Overall Survival Cohort.* In relapsed patients who did not receive ONC201, the median overall survival following first disease progression was 5.1 months. This is in contrast to the data from the 2021 BICR which showed a median OS of 13.7 months from the start of ONC201 treatment following disease progression. Rates of survival at 12 (57% (95% CI: 41 - 70%)) and 24 months (35% (95% CI: 21 - 49%)) in the ONC201 Phase 2 analysis were approximately 2 - 3 times the rates observed in this analysis of patients who did not receive ONC201 (survival at 12 (24% (95% CI: 12-38%)) and 24 months (11% (95% CI: 3.3-24.2))).
- *Objective Response Cohort.* The Company also evaluated objective response by RANO-HGG criteria in patients who received therapies other than ONC201 but met similar selection criteria used for the Phase 2 analysis of ONC201 designed to isolate single agent responses in the recurrent setting. In the two patients who were evaluable, neither achieved an objective response. The low number of patients who qualified was primarily due to the high prevalence of ONC201, bevacizumab and/or radiotherapy use following relapse, which would confound an objective response determination.

Fast Track Designation by FDA

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 diffuse glioma, and Orphan Drug Designations for the treatment of glioblastoma and for the treatment of malignant glioma.

ONC201 in Other Cancers

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 enrolled in 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 Response Evaluation Criteria in Solid Tumors (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 recurrent metastatic paraganglioma patients receiving ONC201 monotherapy 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 four of eight 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 a second generation imipridone and potent ClpP agonist and DRD2 antagonist that penetrates the blood-brain barrier. ONC206 exhibits approximately ten-fold greater potency relative to ONC201 across numerous cancer cells types in vitro and has demonstrated anti-tumor activity in preclinical models of difficult-to-treat neuroendocrine tumors, endometrial cancer, triple negative breast cancer and high-grade gliomas. The multimodal anti-cancer mechanism of ONC206 is driven by disruption of metabolic and epigenetic pathways in tumor cells via activations of the mitochondrial ClpP.

Currently, we are enrolling ONC206 dose escalation trials with a more frequent dosing schedule with the goal of increasing the duration of therapeutic exposure. ONC206 for adults with recurrent primary central nervous system tumors is ongoing at the National Institute of Health (NCT04541082) and at the Pacific Pediatric Neuro-Oncology Consortium (PNOC), for pediatric patients with central nervous system tumors.

In March 2023, the Company reported an investigator-assessed response in a patient with recurrent glioblastoma without the H3K27M-mutation. To date, ONC206 is generally well tolerated with a similar safety profile in adults and pediatrics. No dose limiting toxicities have been identified to date.

Early Pipeline Development, ONC212 and CMX521

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.

Initial IND-enabling studies with ONC212 have been completed and pre-clinical studies are on-going in collaborations with the University of Texas MD Anderson Cancer Center and Brown University. These preclinical studies look to evaluate potential oncology indications and predictive ONC212 biomarkers that could be suitable for clinical development.

CMX521 is a nucleoside analog antiviral drug candidate for the treatment of SARS-CoV-2. CMX521 is not mutagenic, clastogenic, or associated with mitochondrial toxicity. In addition, oral CMX521 demonstrated a favorable profile in GLP toxicology studies and was well-tolerated up to 2,400 mg in a healthy volunteer Phase 1 study for a different indication.

Pursuant to a 2006 agreement between the Company and The Regents of the University of Michigan (UM), the Company obtained an exclusive, worldwide license to UM's patent rights (the UM Patent Rights) in certain inventions related to certain compounds originally synthesized at UM, including CMX521. Under the license agreement, the Company is permitted to research, develop, manufacture and commercialize products utilizing the UM Patent Rights, and to sublicense such rights subject to certain sublicensing fees and royalty payments.

The Company is currently working with the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC) which is the co-recipient of a grant for approximately $1.7 million from the state of North Carolina for the development of CMX521 as a potential treatment for SARS-CoV-2. 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. The grant will fund prodrug synthesis and animal studies to optimize delivery of CMX521 to the lungs via a convenient oral formulation. In addition, UNC will conduct COVID-19 disease mouse efficacy models and evaluate lung delivery of the active antiviral.

Chimerix Antiviral Chemical Library

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 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 (for example, COVID-19) or other potential future pandemics.

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 August 26, 2022, the Company entered into a procurement contract (the BARDA Agreement) with BARDA for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA® to the U.S. government. The BARDA Agreement consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years, if necessary.

On September 26, 2022, the Company sold its exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale) to Emergent. Upon closing of the Asset Purchase Agreement for the Asset Sale, the Company received $238 million upfront and could receive additional milestone payment of up to $136.5 million to be paid contingent upon the execution of optional future procurement awards from BARDA and other development milestones. The Company may also earn a 20% royalty on future gross profit of TEMBEXA in the United States associated with volumes above

1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA. The agreement also allows the Company to earn a 15% royalty on all gross profit associated with TEMBEXA sales outside of the United States during the exclusivity period of TEMBEXA on a market-to-market basis.

The Company continues to provide operational support to Emergent in furtherance of its obligations under both the Asset Purchase Agreement (and related agreements) and the BARDA Agreement. The BARDA Agreement was novated to Emergent in December 2022.

Our Strategy

The principal components of our business strategy are to:

- **Successfully execute the randomized controlled Phase 3 ACTION study.** ONC201 is being developed for H3 K27M-mutant diffuse glioma. Currently, we are enrolling ACTION, a randomized, double-blind, placebo-controlled, multi-center Phase 3 international trial for newly diagnosed patients with H3 K27M-mutant diffuse glioma shortly following radiation with targeted enrollment of approximately 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Available Phase 2 data demonstrate durable responses (as measured by RANO) in recurrent H3 K27M-mutant diffuse midline glioma associated with other forms of clinical benefit. The Phase 2 program was designed to isolate single agent activity in difficult treatment settings. Independent and company sponsored natural disease history studies support a potential survival advantage. The genetically selected patient population limits patient heterogeneity. In the current neuro-oncology community there exists high awareness of ONC201 which we believe will aid in the enrollment of this study.
- **Upon approval, successfully commercialize ONC201.** Patients with H3 K27M mutant diffuse glioma are faced with a terminal disease with no known effective therapeutic options beyond radiation. In the current neuro-oncology community there exists high awareness of ONC201 which we believe will aid in the potential commercialization. The global potential annual revenue of ONC201 for its first indication exceeds ~$750 million, based on our internal estimates.
- **Maintain corporate capability and financial flexibility.** Our leadership team has successfully executed large-scale clinical studies and regulatory approvals of investigational agents. We intend to continue to leverage external capital to develop our early-stage pipeline consisting of ONC206, ONC212 and derivatives of CMX521.
- **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, 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

Emergent Biodefense Operations Lansing LLC

On September 26, 2022, the Company completed the Asset Sale to Emergent of the Company's exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale). Emergent paid the Company an upfront cash payment of approximately $238 million upon the closing of the Asset Sale. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from Emergent: (i) up to an aggregate of approximately $124 million in milestone payments payable upon the exercise of the options under the BARDA Agreement for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA to the U.S. government; (ii) royalty payments equal to 15% of the gross profits from the sales of TEMBEXA made outside of the United States; (iii) royalty payments equal to 20% of the gross profits from the sales of TEMBEXA made in the United States in excess of 1.7 million treatment courses; and (iv) up to an additional $12.5 million upon the achievement of certain other developmental milestones.

The Company continues to provide operational support to Emergent in furtherance of its obligations under both the Asset Purchase Agreement (and related agreements) and the BARDA Agreement. The BARDA Agreement was novated to Emergent LLC in December 2022.

Merger Agreement with Oncoceutics

On January 7, 2021, we entered into an agreement 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) made an additional cash payment of $14.0 million 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 combined future net sales of ONC201 and ONC206 products of 15% up to $750 million in annual revenue and 20% above $750 million in annual revenue, 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. Pursuant to the merger agreement we have certain diligence obligations with respect to further development and commercialization of the Oncoceutics product candidates.

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 for ONC201 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

If ONC201 is approved for H3 K27M-mutant diffuse glioma, we plan to commercialize ONC201 in the United States. We anticipate that commercialization 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 ourselves or through distribution or other collaboration arrangements. If we elect to develop ONC201 for other indications, we will 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 ONC201 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 ONC201 or any product candidate, 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 (selinexor, paxalisib, MDNA55), and other therapies.

Changes in the health care system may limit our ability to price ONC201 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 ONC201 has potential benefits over existing and potential competitive products, and, as a result, we believe that our 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.

Imipridone Patent Portfolio

At February 12, 2024, our worldwide imipridone patent portfolio included:

- 441 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 225 US and foreign issued patents and 68 pending US and foreign applications related to ONC201; and
- Patent protection for ONC201’s lead indication is expected to extend into 2037 in the U.S., with the potential for additional patent term extension.

Antiviral Patent Portfolio

At February 12, 2024, our worldwide antiviral patent portfolio included:

- 26 patents or patent applications that we own or have in-licensed from academic institutions, related to antivirals, which represented a decrease over the number of patents in our patent portfolio at the end of fiscal year 2022;
- This includes 17 US and foreign exclusively and jointly owned patents and 9 US and foreign applications related to antivirals. Granted European patents are counted as one patent and have been validated throughout Europe;
- Six jointly-owned 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, two US patent applications, and one European patent application exclusively owned by Chimerix directed to a morphic form of a compound from the Chemical Library.

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 portfolio, enhancing our freedom of action to exclusively sell our products, 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 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 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 ONC201, our expanded access program for ONC201 and other clinical trials as well as for commercial purposes should ONC201 be approved. When produced on a commercial scale, we expect that cost-of-goods-sold relating to the imipridone class of assets will generally be in-line with that of other targeted oncology therapies.

The manufacturing processes for ONC201 drug substance and drug product are relatively straight-forward and generally in-line with other small molecule pharmaceutical compounds in terms of cost and complexity. The processes are robust and reproducible and do not require dedicated reactors or specialized equipment. The drug substance process uses common synthetic chemistry and readily available materials, including off-the-shelf and made-to-order starting materials, and is readily transferable. The drug product process uses common excipients and readily available materials, and is also readily transferable.

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 for ONC201. We continually assess our manufacturing needs and may seek to engage additional qualified vendors as circumstances dictate. 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.

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, EU or in other countries by the responsible national regulatory agency.

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 two 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

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.

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.

U.S. 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. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

There have been, and we expect that there will continue to be a number of federal and state proposals and enacted legislation to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs.

For example, 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, 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. The ACA may be subject to additional judicial or Congressional challenges in the future. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact ACA.

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, for example, 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, the U.S. Department of Health and Human Services (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 to advance these principles. Additionally, the IRA, among other things, (i) directs DHHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits DHHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. 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 five 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 to 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, 2023, we had 72 full-time employees. Of these employees, 56 employees are engaged in research and development activities and 16 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 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.

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 in each year since our inception other than 2022. We anticipate that we will continue to incur significant losses for the foreseeable future.

We are a biopharmaceutical company focused primarily on developing ONC201 for the treatment of H3 K27M-mutant diffuse glioma as we also evaluate programs to advance from our earlier stage pipeline. We have incurred significant net losses in each year since our inception other than 2022, including a net loss of $82.1 million for the twelve months ended December 31, 2023. As of December 31, 2023, we had an accumulated deficit of approximately $795.5 million.

To date, with the exception of the Asset Sale, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, through government funding, licensing fees, the sales of TEMBEXA product and debt. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We expect to 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 H3 K27M-mutant diffuse glioma, and other potential indications;
- obtain regulatory approvals for ONC201 and other imipridones;
- scale-up manufacturing capabilities for ONC201 and other imipridones;
- 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.

We obtained regulatory approval for and initially commercialized TEMBEXA, however, none of our other 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.

Although we achieved profitability in 2022 as a result of the closing of our Asset Sale with Emergent Biodefense Operations Lansing LLC (Emergent), we were not profitable in 2023, and 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:

- obtaining favorable results for and advancing development of imipridones, including ONC201 for the treatment of H3 K27M-mutant diffuse glioma, and other potential indications;
- obtaining United States regulatory approval for ONC201 and other pipeline assets;
- obtaining foreign regulatory approval(s) for ONC201 and other pipeline assets;
- 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 activate, enroll, and complete, and we may never successfully enroll a sufficient number of patients or 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.

Further, 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 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 the Phase 3 ACTION Study, a registrational study for H3 K27M-mutant diffuse 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 ONC201, or any other product candidate;
- seek corporate partners for ONC201, 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 Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank, now a division of First-Citizens Bank & Trust Company, effective January 31, 2022, as amended on November 21, 2023, 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. Our obligations under the Loan Agreement are secured by a first priority perfected security interest in substantially all of our assets other than our intellectual property, subject to certain 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 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 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 these matters 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

All of our 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 of our current product candidates. Our most advanced product candidate is ONC201, which we are developing for the treatment of H3 K27M-mutant diffuse glioma. In November 2022, we initiated a Phase 3 clinical study of ONC201 (the Phase 3 ACTION Study), and it is possible that a single trial to support regulatory approval may not be sufficient.

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 any of our product candidates will depend on several factors, including the following:

- generating positive safety and efficacy data from our clinical trials of ONC201;
- receipt of marketing approvals from the FDA and corresponding regulatory authorities outside the United States;
- establishing commercial manufacturing capabilities;
- 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 our product candidates, including ONC201, 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 candidate: ONC201.

In January 2021, we acquired Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, a novel potential class of compounds. Oncoceutics's lead product candidate, ONC201, is currently being evaluated in the Phase 3 ACTION Study, and multiple investigator-sponsored clinical studies.

We have reached general agreement with the FDA on the design of the Phase 3 ACTION Study to support a potential approval for marketing. We have not yet reached agreement with foreign regulators regarding the adequacy of the planned studies, for any of our 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 consideration 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.

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, 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. 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, 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. In the case of ONC201, early studies were open label studies of brain tumor patients, whereas the ongoing Phase 3 ACTION Study is a double blinded, placebo-controlled, investigational study. 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 outside our control;
- 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. 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 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.

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, in our Phase 2 study of ONC201, 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. 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 any of our product candidates, including ONC201.

We cannot commercialize our product candidates, including ONC201, 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 to

support accelerated approval or be conducted to pursue a first full approval. For ONC201, a companion diagnostic test may be needed to identify patients with H3 K27M-mutant diffuse glioma. 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, standard of care diagnostic tests are used to identify patients with H3 K27M-mutant diffuse glioma. Currently, such tests are available as a Laboratory Developed Test, or LDT, that has not been cleared or approved by FDA as a companion diagnostic test. FDA may require approval of a companion diagnostic in connection with an approval of an ONC201 NDA. We intend to rely on third parties for development of companion diagnostics for commercialization of ONC201, if required. 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 may impair our ability to meet FDA requirements for ONC201 and subsequently jeopardize or delay a potential marketing authorization.

The FDA may determine that ONC201 or any of our other product candidates, even if approved for the designated rare pediatric disease prior to September 30, 2026, 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 diffuse 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 diffuse 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. Absent any legislative 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. In the event that the Company receives a priority review voucher for ONC201, any proceeds related to the voucher would be subject to potential adjustment according to the terms of our merger agreement with Oncoceutics.

Following regulatory approval for any of our product candidates, including ONC201, 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 our product candidates, including ONC201, 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.

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.

We may never obtain approval for or commercialize any of our 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 of our 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 Chimerix has limited 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, 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, 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. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. 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 healthcare professional 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 certain 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. However, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, 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. It is possible that the ACA will be subject to additional 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, 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, the U.S. Department of Health and Human Services (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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, (1) directs the DHHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits DHHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. DHHS has and will continue to issue and update guidance as these programs as implemented. These provisions have begun taking effect progressively starting in fiscal year 2023. On August 29, 2023, DHHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how certain aspects of the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. While the IRA predominantly focuses on controlling spending of drugs that are covered by Medicare, and our product candidates, if approved, are not expected to target the Medicare population, other similar legislation may be implemented in the future that may be broader in scope and may adversely affect our operations, including our ability to commercialize our product candidates, if approved, successfully. In response to the Biden administration's October 2022 executive order, on February 14, 2023, DHHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain pharmaceutical products from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. 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. 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.

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 our product candidates, including ONC201. 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.

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 outside our control;
- 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.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay or impair commercialization of ONC201 or our other product candidates.

We plan to validate 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 ONC201 with the FDA. If supply is interrupted, there could be a significant disruption in the clinical supply. An alternate vendor would need to be qualified which could result in a further delay.

As more batch data is generated during both pre- and 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 ONC201.

The anticipated benefits of the sale of our TEMBEXA program and related assets may not be realized fully or at all or may take longer to realize than expected.

In September 2022, we completed the sale of our TEMBEXA program and related assets to Emergent. Under the terms of the sale, we are entitled to contingent consideration, including milestone payments and royalties, dependent upon the further development and commercial success of TEMBEXA. Accordingly, our ability to receive the contingent consideration will depend, in part, on Emergent's ability to successfully develop and commercialize TEMBEXA. If Emergent is unable to successfully or timely integrate TEMBEXA operations into its business, it may not be able to realize the revenue growth, milestone achievements, synergies and other anticipated benefits resulting from the Asset Sale, and consequently, we may not receive all, or any, of the contingent payments under the Asset Purchase Agreement. The milestones set forth in the Asset Purchase Agreement may not be achieved on a timely basis, if at all, and we may not receive any future contingent payments. Any failure to achieve such milestones, or a perception that the milestones may not be achieved, may adversely affect our business and the value of our common stock.

Moreover, in 2019, we entered into a licensing arrangement with SymBio Pharmaceuticals (SymBio), whereby SymBio is responsible for the future development and commercialization of TEMBEXA for human diseases other than orthopoxviruses, including smallpox. In connection with the sale of TEMBEXA worldwide rights to Emergent, our rights and obligations under the SymBio license agreement were assumed by Emergent. We could receive up to $12.5 million from Emergent in brincidofovir regulatory milestones related to the SymBio license agreement. Our right to receive milestone payments under the Asset Purchase Agreement depends on the achievement of certain regulatory milestones by SymBio in the licensed indications.

The development and commercialization of the non-orthopox uses of TEMBEXA in humans and our ability to receive potential milestone payments under the Asset Purchase Agreement, would be adversely affected if SymBio:

- lacks or does not devote sufficient time and resource to the development of TEMBEXA;
- lacks or does not devote sufficient capital to fund the development of TEMBEXA;

- develops, either alone or with others, products that compete with TEMBEXA;
- fails to gain the requisite regulatory approvals for TEMBEXA;
- does not conduct its activities in a timely manner;
- terminates its license with Emergent;
- 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. If any of these issues arise, it may delay or eliminate our ability to receive the regulatory milestones in the Asset Purchase Agreement.

Emergent may not adequately perform according to the terms of the BARDA Agreement, and we might be required to guarantee performance of all obligations that Emergent assumed under novation.

As required by U.S. government contracting regulations, the novation agreement for the BARDA Agreement includes a clause requiring that Chimerix, as transferor, guarantee Emergent's performance of the BARDA Agreement. If Emergent were to fail to manufacture or deliver treatment courses of TEMBEXA, fail to properly respond to a product recall, or breach other performance obligations, BARDA may require that we perform instead, which may cause us to file claims under our insurance policies, divert the attention of our management from company priorities, expend additional resources engaging vendors, require additional legal agreements with Emergent to enable Chimerix to resume title to TEMBEXA and control of supply chain vendors necessary for performance, incur additional legal fees, among other unplanned expenses which could delay or prevent our completion of our priority clinical programs, as well as result in reputational harm.

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 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 ONC201, 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 agencies.

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 our other product candidates, including ONC201, 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 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.

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 sustainably generate 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 ONC201, 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, 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 any of our drug candidates that we are currently developing or that we may develop including ONC201.

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, 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 ONC201; 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 an approved product 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, 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 or suppliers of grey-market goods, 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. We have recently initiated patent infringement proceedings in a jurisdiction outside the United States against a supplier in contravention of certain patents we own or license covering ONC201 and ONC206.

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 Business Operations and Industry

Increasing demand for compassionate use or third-party supply of our unapproved therapies could impair or delay the completion of our controlled clinical trials or otherwise 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, we had previously been 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 our product candidates 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 or may delay or prevent the regulatory approval of our products.

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.

Patient demand for ONC201 or ONC206 outside of our clinical trial could impair the conduct or delay the completion of our controlled clinical trials. Currently, there are a limited number of therapeutic options available to glioma patients suffering from this severe and life-threatening disease. In the face of a glioma diagnosis, patients will often turn to alternate means of access to drug outside the scope of our current clinical trials. We are, and from time to time may be, aware of such counterfeit providers that purport to supply ONC201, ONC206 or similar versions thereof. We have taken and intend to continue taking meaningful action to eliminate such counterfeit supplies when and if appropriate. For example, we have initiated patent and trademark infringement litigation and unfair trade practice claims in a jurisdiction outside of the United States against identified sources of counterfeit supplies for ONC201 and ONC206, seeking among other things to enjoin the availability of such counterfeit supplies. These claims, and any similar actions we take, may not be successful or may take longer than anticipated to reduce or eliminate counterfeit supplies. If a significant number of patients continue to choose counterfeit supplies from third parties rather than enroll in our studies, our clinical program could be negatively impacted. In the event that patients choose to access counterfeit supplies while enrolled in our clinical studies, we may not be able to successfully meet the study endpoints and our clinical program could be negatively impacted.

We have amended the protocol of our open expanded access program to focus on patients that are not eligible for the Phase 3 ACTION Study. Therefore, the Phase 3 ACTION Study will serve as the main mechanism for patients with newly diagnosed H3 K27M-mutant diffuse glioma following completion of radiotherapy to receive ONC201, apart from such counterfeit providers discussed above. This decision could prompt adverse publicity, could drive potential Phase 3 ACTION Study patients to seek drugs that purport to be ONC201 or ONC206 from counterfeit providers, or cause other disruptions related to potential participants in such expanded access programs.

Competition for Phase 3 ACTION Study eligible patients from Investigator Initiated Clinical Trials (IITs) could result in losses.

We currently provide investigational product for the Biological Medicine for Diffuse Intrinsic Pontine Glioma (DIPG) Eradication (BIOMEDE 2.0) IIT, sponsored by Gustave Roussy, in Paris, France. The BIOMEDE 2.0 Study is a multicenter, randomized open-label phase-3 controlled trial evaluating the efficacy and safety of ONC201 and radiation in comparison with everolimus and radiation (primary objective based on internal comparison) and subsequently to historical controls. Currently, the BIOMEDE 2.0 Study is open in France to pre-radiotherapy newly diagnosed H3 K27M and H3 K27me3-loss glioma patients. Some of these patients may be eligible for the Phase 3 ACTION Study following radiotherapy. While we believe that the impact is likely to be small in light of the small geographic footprint and limited eligibility overlap, competing enrollment could have a negative effect on our ability to enroll the Phase 3 ACTION Study. Patients may prefer to enroll in the BIOMEDE 2 IIT instead of the Phase 3 ACTION Study because that study does not contain a placebo control arm, cross-over is allowed at progression, and treatment can be initiated with radiation. Patient preference for the BIOMEDE 2 IIT could impair the conduct or delay the initiation or completion of the Phase 3 ACTION Study. If completion of the Phase 3 ACTION Study is delayed, our development costs may increase, our approval process could be delayed, any periods during which we may have the exclusive right to commercialize ONC201 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. We previously worked with another IIT sponsor to amend the protocol to remove potentially Phase 3 ACTION Study eligible patients. This decision could prompt adverse publicity or other disruptions related to potential participants in the IITs. While the Company has negotiated a right to obtain access to the data from the BIOMEDE 2.0 Study at a specified price should the Company desire to do so in support of a commercial authorization, there is no assurance that the Company will be able to enter into a definitive agreement.

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 manage our recent management transition, retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team. Effective August 1, 2023, Michael Sherman retired from his role as President and Chief Executive Officer of the Company, and Michael Andriole, Chief Business Officer and Chief Financial Officer, was promoted to President and Chief Executive Officer. During the fourth quarter of 2024, Michelle LaSpaluto was promoted to the position of Chief Financial Officer and Thomas J. Riga was hired as Chief Operating Officer and Chief Commercial Officer of the Company.

Our future performance will depend, in part, on the successful integration of these management changes. If we do not successfully manage these changes, it could be viewed negatively by our employees, investors, and other third-party partners, and could have an adverse impact on our business and results of operations.

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. As of December 31, 2023, approximately 99.5% of all outstanding options had an exercise price above the closing price of the stock on that date. As a result, the current situation provides a considerable challenge to maintaining employee motivation, as well as creating a serious threat to retention until a recovery commences. 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.

The share reserves under our 2013 Equity Incentive Plan (the 2013 Plan) and 2013 Employee Stock Purchase Plan (ESPP) were previously subject to automatic annual increases on January 1st of each year. At this time, subject to limited exceptions, we are required to seek stockholder approval of future increases to the number of shares underlying our 2013 Plan (or a successor plan) and ESPP. In the event we are unable to obtain stockholder approval of such future increases, our ability to attract, retain and motivate employees through the use of share-based compensation would be substantially curtailed.

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, in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, 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 our product candidates, including ONC201; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently carry $15 million per occurrence, and $15 million in the aggregate in product liability insurance covering our United States clinical trials, with additional local coverage as required for the other countries in which we conduct our 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.

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 our product candidates, including ONC201;
- termination of any of our license or collaboration agreements;
- developments regarding the sale of our TEMBEXA program and specified related assets to Emergent;
- 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; 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, 2023, our then executive officers, directors, 5% stockholders (known to us through available information) and their affiliates beneficially owned approximately 28.9% 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 Global 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.

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. For example, 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 the 2013 Plan, our management is authorized to grant stock options to our employees, directors and consultants. 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). To the extent we seek, and our stockholders approve, future increases to the number of shares underlying our 2013 Plan (or a successor plan) and ESPP, 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 investment-grade, interest-bearing securities with maturities less than 24 months. 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 tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, or modified. Any such enactment, interpretation, change or modification could adversely affect us, possibly with retroactive effect. For example, the IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. In addition, for certain research and experimental expenses incurred in tax years beginning after December 31, 2021, the Tax Cuts and Jobs Act (the Tax Act) requires the capitalization and amortization of such expenses over five years if incurred in the United States and fifteen years if incurred outside the United States, rather than deducting such expenses currently. There have been legislative proposals to repeal or defer the research and experimental expense capitalization rules, including legislation recently passed by the U.S. House of Representatives that would restore the deductibility of U.S. based research and experimental expenses but not non-U.S. research and experimental expenses, but there can be no assurance that any such legislation will ultimately be enacted. 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 as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) or any future tax 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.

As of December 31, 2023, we had net operating loss (NOL) carryforwards of $423.2 million and $416.0 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. Our federal NOLs generated in tax years beginning before January 1, 2018, are only permitted to be carried forward for 20 years under applicable U.S. tax law. If not utilized, our federal and state NOL carryforwards begin to expire in 2035 and 2024, respectively. Portions of these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, as amended by the CARES Act, our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), 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 certain other pre-change federal tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our federal carryforwards and certain other pre-change federal tax attributes (such as research tax credits) to offset our post-change income or taxes could be limited. 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 NOL carryforwards is suspended or otherwise limited. As a result, we may be unable to use all or a material portion of our state NOL carryforwards and other state tax attributes, which could accelerate or permanently increase state taxes owed.

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 Data Privacy

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

We process personal data and other sensitive information, which subjects us to numerous evolving data privacy and security obligations. In the ordinary course of business, we collect, receive, store, process, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, and other sensitive data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade

Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, we are subject to the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR) (collectively, GDPR). Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the GDPR/ 17.5 million pounds sterling under the UK GDPR, or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. The Swiss Federal Act on Data Protection (FADP) also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA), Switzerland, and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA, Switzerland, and United Kingdom to the United States in compliance with law, such as the EEA standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the United Kingdom extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, Switzerland, the United Kingdom or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA, Switzerland, and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed,

to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to Information Technology

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, trade secrets and any other sensitive data.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation clinical trial data processing, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-

related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate such vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents, including affected individuals, customers, regulators, and investors. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management's attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 1C. CYBERSECURITY

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to ongoing or previous clinical trials. (Information Systems and Data).

Our CEO and CFO, along with our Legal, Quality Assurance (QA), and IT (Information Technology) departments help identify, assess and manage the Company's cybersecurity threats and risks. The IT department works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, manual and automated tools, subscribing to reports and services that identify cybersecurity threats, evaluating threats reported to us, internal and external audits, and utilizing trusted third parties to conduct vulnerability assessments to identify vulnerabilities.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, our incident response policy, incident detection and response procedures, encryption of certain data, network security controls, and data segregation across certain of our environments, access controls, physical security, systems monitoring, employee cybersecurity training, penetration testing conducted by third-parties, and maintaining cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, the IT department works with management to prioritize our risk management processes and to mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us in identifying, assessing, and managing certain material risks from cybersecurity threats, including for example, data protection and privacy compliance professional service providers, external legal counsel, cybersecurity software providers, penetration testing firms, and managed cybersecurity service providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, contract research organizations, contract manufacturing organizations, distributors, and supply chain resources. We have a vendor qualification and management program designed to manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider. For example, we may conduct vendor qualification audits that assess a potential third party's cybersecurity risk potential. We may conduct a vendor risk assessment that evaluates the likelihood and potential impact of a cybersecurity threat involving the third-party service provider, based on factors such as the type and scope of services, the data processed, and the third-party service provider's security practices. We may request security attestations and certifications to verify that the vendor has met the relevant industry standards and best practices for cybersecurity. We may establish security clauses in our agreements with third-party service providers that address such matters as the roles, responsibilities, and expectations of both parties regarding cybersecurity, such as the security policies and procedures, the incident response and notification expectations, the remediation measures to be adopted, the responsibility for losses associated with incidents.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the "Risks Related to Information Technology." The Company has not experienced a cybersecurity threat that has materially affected the company.

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Board of Directors' Audit Committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.
Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Senior Director of Information Technology and Senior Manager of Information Technology. Combined they have more than 35 years of experience in IT and cybersecurity. They hold many industry certifications in areas including Risk Management, Cybersecurity, Digital Forensics, Networking, and Enterprise Architecture. Their previous positions include work in Security Operations Centers and cybersecurity consulting for Fortune 500 companies and critical infrastructure providers.

The Information Technology and Legal departments are responsible for helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy and communicating key priorities to relevant personnel. The Senior Director of Information Technology, Senior Manager of Information Technology, and Assistant General Counsel are also responsible for helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including Legal, the CFO, the CEO, and the IT department. Chimerix follows the cybersecurity incident response policy to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy includes reporting to the Audit Committee of the Board of Directors for certain cybersecurity incidents.

The Audit Committee of the Board of Directors receives quarterly reports from the Senior Director of IT concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented (or plans to implement) to address them. The Audit Committee of the Board of Directors also may request various reports, summaries or presentations related to cybersecurity threats, risk, and mitigation.

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.

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

Our Common Stock is listed and traded on the Nasdaq Global Market under the trading symbol "CMRX."

Stockholders

As of February 23, 2024, there were 71 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 Loan Agreement may prohibit us from declaring or paying dividends.

Recent Sales of Unregistered Securities

None.

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 our audited 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. The Company is focused on developing imipridones as a potential new class of selective cancer therapies. The most advanced imipridone is dordaviprone (ONC201) which is in clinical-stage development for H3 K27M-mutant diffuse glioma as its lead indication. In addition, a second-generation imipridone (ONC206) is currently in dose escalating clinical trials for adult and pediatric patients with primary central nervous system tumors.

Recent Developments

Dordaviprone, ONC201

Phase 3 ACTION Study Continues - Interim Data Expected in 2025

The Phase 3 ACTION trial is currently enrolling patients at over 130 sites in 13 countries in North America, Europe, the UK, Israel, Australia and Asia. Management expects interim overall survival (OS) data from the trial to occur in 2025 with a final OS data expected in 2026. The ACTION trial enrolls patients shortly after they have completed front-line radiation therapy that is the standard of care for glioma. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Participants will be randomized to receive either: (i) 625mg of ONC201 once per week, (ii) 625mg twice per week on two consecutive days or (iii) placebo. The study is open to pediatric and adult patients >10kg body weight and the dose will be scaled by body weight for patients weighing less than 52.5kg. Primary endpoints include OS and PFS. OS will be assessed for efficacy at three alpha-allocated timepoints consisting of two interim assessments by the Independent Data Monitoring Committee (IDMC) at 164 events and 246 events, respectively, and a final assessment at 327 events. The final PFS analysis will be performed after 286 events, with progression assessed using response assessment in neuro-oncology-high grade glioma (RANO HGG) criteria by blinded independent central review (BICR). Secondary endpoints include corticosteroid response, performance status response, change from baseline in quality of life (QoL) assessments and change from baseline in neurologic function as assessed by the Neurologic Assessment in Neuro-Oncology (NANO) scale. Per the protocol, a safety interim analysis will be completed after the first 120 patients have been treated and followed for at least three cycles.

Our plan is to initiate a submission to regulators for approval upon receipt of positive overall survival data at either of the interim or the final overall survival analyses. In addition, in the event the result of the progression free survival analysis is positive, we would discuss the potential for submission of ONC201 with regulatory authorities based on this data, which may lead to a potential accelerated approval, a type of temporary marketing authorization that is contingent on future data, such as a positive overall survival analysis.

Journal of Clinical Oncology Publication

In February 2024, “ONC201 (dordaviprone) in Recurrent H3 K27M-mutant Diffuse Midline Glioma,” was published in the Journal of Clinical Oncology (JCO), a peer reviewed journal of the American Society of Clinical Oncology (ASCO). The manuscript reports in detail the results of 50 patients with recurrent H3 K27M-DMG treated with monotherapy ONC201 who were evaluable for objective response by Response Assessment in Neuro-Oncology (RANO) high grade glioma (HGG) criteria. ONC201 demonstrated a median overall survival (mOS) of 13.7 months (95% CI: 8.0-20.3), with an overall two-year rate of survival of 35% (95% CI: 21-49) from the start of ONC201 treatment post-recurrence. The Company previously conducted a natural disease history study (n=43) in the recurrent setting evaluating patients who did not receive ONC201 which showed a mOS of 5.1 months (95% CI: 3.9-7.1) with an overall two-year survival rate of 11% (95% CI: 3.3-24.2). The top-line data from this JCO publication were previously disclosed by the Company. The journal can be accessed at https://ascopubs.org/doi/10.1200/jco.23.01134.

Cancer Discovery Publication

In August 2023, data in support of ONC201 as a treatment for H3 K27M-mutant diffuse midline gliomas (H3K27M-DMG) appeared in the peer-reviewed journal, Cancer Discovery, a journal of the American Association for Cancer Research. The manuscript titled, “Clinical efficacy of ONC201 in H3K27M-mutant diffuse midline gliomas is driven by disruption of integrated metabolic and epigenetic pathways,” reported survival analyses of 71 patients with H3K27M-DMG treated with ONC201, which demonstrated promising results in a patient population with a poor prognosis and few treatment options. In addition to assessing clinical outcomes, the study corroborated mechanistic findings from laboratory models in samples from treated patients that demonstrated the ability of ONC201 to disrupt metabolic pathways and reverse a molecular signature of the H3 K27M mutation in patient's tumor samples. According to the survival analyses in this study, ONC201 frontline treatment, administered post radiation therapy, demonstrated a significant increase in median overall survival (mOS) from diagnosis in ONC201-treated versus in historical controls (21.7 months mOS vs. 12 months mOS, p<0.0001). The study was led by a team of researchers from the University of Michigan and other collaborators including several authors from Chimerix. The journal can be accessed at https://aacrjournals.org/cancerdiscovery/article/13/11/2370/729854/Clinical-Efficacy-of-ONC201-in-H3K27M-Mutant.

Early Pipeline Development – ONC206, ONC212 and CMX521

ONC206

ONC206 is a second generation DRD2 antagonist and ClpP agonist that has demonstrated monotherapy anti-cancer activity in pre-clinical models. ONC206 is currently being evaluated in Phase 1 dose escalation trials enrolling patients with advanced central nervous system tumors in partnership with the National Institutes of Health (NIH) and with the Pacific Pediatric Neuro-Oncology Consortium (PNOC). In March 2023, the Company reported an investigator-assessed response in a patient with recurrent glioblastoma without the H3K27M-mutation. To date, ONC206 is generally well tolerated with a similar safety profile in adults and pediatrics. No dose limiting toxicities have been identified to date. We are currently enrolling ONC206 dose escalation trials with a more frequent dosing schedule to increase the duration of therapeutic exposure. We expect to report preliminary safety and pharmacokinetic data from these trials beginning in mid-2024.

ONC206 is in ongoing nonclinical studies to identify and evaluate candidate biomarker-defined oncology indications, to identify potential pharmacodynamic biomarkers and further elucidate its mechanism of action. These activities will inform data-driven clinical development plans.

ONC212

ONC212, which targets GPR132 and ClpP, has completed IND-enabling toxicology studies. ONC212 is being explored pre-clinically in collaborations with MD Anderson Cancer Center and Brown University. Furthermore, preclinical studies are ongoing to evaluate potential oncology indications and predictive biomarkers for ONC212 that could be suitable for clinical development.

CMX521

CMX521 is a nucleoside analog antiviral drug candidate for the treatment of SARS-CoV-2. CMX521 is not mutagenic, clastogenic, or associated with mitochondrial toxicity. In addition, oral CMX521 demonstrated a favorable profile in GLP toxicology studies and was well-tolerated up to 2,400 mg in a healthy volunteer Phase 1 study for a different indication.

Pursuant to a 2006 agreement between the Company and The Regents of the University of Michigan (UM), the Company obtained an exclusive, worldwide license to UM's patent rights in certain inventions related to certain compounds originally synthesized at UM, including CMX521. Under the license agreement, the Company is permitted to research, develop, manufacture and commercialize products utilizing the UM Patent Rights, and to sublicense such rights subject to certain sublicensing fees and royalty payments.

We are currently working with the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC) for the development of CMX521 as a potential treatment for SARS-CoV-2. UNC which is the co-recipient of a grant for approximately $1.7 million from the state of North Carolina which will defray the majority of the costs on this effort. The grant will fund prodrug synthesis and animal studies to optimize delivery of CMX521 to the lungs via a convenient oral formulation. In addition, UNC will conduct COVID-19 disease mouse efficacy model studies and evaluate lung delivery of the active antiviral.

Board of Directors Changes

On December 28, 2023, Catherine L. Gilliss, PhD, RN, FAAN retired and resigned as a member of the Board of Directors (Board). The Board appointed Lisa L. Decker, PhD, to serve as a member of the Board to fill the vacancy created by Dr. Gilliss's retirement.

Promotion of Michelle LaSpaluto to Chief Financial Officer

On December 1, 2023, Michelle LaSpaluto was promoted to the position of Chief Financial Officer of the Company. Prior to her promotion as the Company's Chief Financial Officer of the Company, Ms. LaSpaluto served as the Company's Vice President of Corporate Financial Planning and Investor Relations since October 2019, as Executive Director of Financial Planning, Analysis and Investor Relations from January 2016 to October 2019, and as Senior Director of Accounting from June 2011 to October 2019.

Appointment of Thomas J. Riga as Chief Operating Officer and Chief Commercial Officer

On November 16, 2023, Thomas J. Riga was hired as Chief Operating Officer and Chief Commercial Officer of the Company. Mr. Riga has over 25 years of pharmaceutical leadership experience.

Business Development Review

In addition to our prior business development transactions, 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, 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 or action.

Financial Overview

Revenues

To date, we have generated modest, non-recurring revenue from product sales. Since inception, other than 2022 which included 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.

Emergent BioSolutions, Inc.

On September 26, 2022, the Company closed the previously disclosed Asset Sale with Emergent. Emergent paid the Company an upfront cash payment of approximately $238 million upon closing. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from Emergent: (i) up to an aggregate of approximately $124 million in milestone payments payable upon the exercise of the options under the BARDA Agreement; (ii) royalty payments equal to 15% of the gross profits from the sales of TEMBEXA made outside of the United States; (iii) royalty payments equal to 20% of the gross profits from the sales of TEMBEXA made in the United States in excess of 1.7 million treatment courses; and (iv) up to an additional $12.5 million upon the achievement of certain other developmental milestones.

The BARDA Agreement was novated to Emergent in December 2022. Under Asset Purchase Agreement, the Company recognized approximately $0.2 million and $0.5 million of contract revenue for support provided for the twelve months ended December 31, 2023 and 2022, respectively.

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) 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. Under the BARDA contract, we recognized contract revenue of $1.6 million during the twelve months ended December 31, 2021.

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. At December 31, 2023, the Company had a deferred revenue balance of $0.1 million related to these grants. Additionally, for the twelve months ended months ended December 31, 2023 and 2022, the Company recognized $30,000 and $0.5 million, respectively, of grant revenue related to these grants.

Ohara Agreement

In 2019, Oncoceutics, Inc., a Delaware corporation (Oncoceutics) which was subsequently acquired by the Company in January 2021, 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 double-digit tiered royalties based on the aggregate annual net sales of all products, as defined in the agreement, in Japan. For the twelve months ended months ended December 31, 2023 and 2022, the Company recognized approximately $58,000 and $0.5 million, respectively, of license revenue related to this agreement.

TEMBEXA Procurement Agreements Revenue and Royalty Revenue

In June 2022, the Company entered into a Supply Agreement (the Supply Agreement) with a third-party outside of North America (the Purchaser), pursuant to which the Company was responsible for supplying to the Purchaser, and the Purchaser was responsible for purchasing from the Company, TEMBEXA treatment courses for use in a jurisdiction outside of the United States. Under the terms of the Supply Agreement, the Purchaser paid the Company an aggregate purchase price of approximately $9.3 million, in two equal installments in June 2022 and July 2022. The Company recognized $9.3 million of procurement revenue under the Supply Agreement for the twelve months ended December 31, 2022.

Additionally, in June 2022, the Public Health Agency of Canada (PHAC) awarded a Contract (the PHAC Contract) to the Company, pursuant to which PHAC agreed to purchase up to approximately $25.3 million (CAD $33.0 million) of TEMBEXA treatment courses for use in Canada. Substantially all of the procurement was delivered and accepted by PHAC in July 2022, completing the performance obligation for those shipments and resulting in $22.6 million of procurement revenue for the twelve months ended December 31, 2022. PHAC assigned the PHAC Contract to Emergent in November 2022. The remaining deliveries of treatment courses were delivered by Emergent and were subject to the royalty terms of the Asset Purchase Agreement applicable to gross profits outside the United States. The Company recognized approximately $0.4 million of royalty revenue in the twelve months ended December 31, 2022.

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);
- 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,		
	2023	2022	2021
Direct research and development expenses	$ 41,875	$ 42,227	$ 26,808
Research and development personnel costs - excluding stock-based compensation	16,287	18,615	17,709
Research and development personnel costs - stock-based compensation	7,092	8,267	6,611
Indirect research and development expenses	3,534	2,522	22,689
Total research and development expenses	$ 68,788	$ 71,631	$ 73,817

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.

Imipridones Program

In January 2021, we acquired Oncoceutics. As we continue to develop and prepare ONC201 for 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 imipridone compounds, including ONC206 and ONC212.

TEMBEXA (Brincidofovir, BCV)

We developed TEMBEXA for the treatment of smallpox. FDA marketing approval for TEMBEXA was received on June 4, 2021 (June 2021 FDA Approval). Under our February 2011 cost-plus-fixed fee development contract with BARDA, 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 procurement contract. These costs were expensed as incurred until the June 2021 FDA approval. Following the approval, costs related to the manufacturing of TEMBEXA are recorded and shown as inventories on the Consolidated Balance Sheets. With the sale of TEMBEXA to Emergent all inventory, prepaids and liabilities associated with TEMBEXA were transferred to Emergent as part of the transaction.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, commercial, 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 accounting and legal services, costs of various consultants, director and officer liability insurance, occupancy costs and information systems.

Gain on Sale of Business, Net

Emergent BioSolutions, Inc.

The previously mentioned sale of TEMBEXA constitutes a significant disposition of a business, however, the Company determined the disposition does not represent a strategic shift, and accordingly, the Company has not accounted for the disposition as a discontinued operation. The Company recorded a $229.7 million net gain on sale of business in other income (loss) on the Consolidated Statement of Operations and Comprehensive Income (Loss) for the twelve months ended December 31, 2022.

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 $17.5 million, $15.3 million and $12.3 million was recognized in the years ended December 31, 2023, 2022 and 2021, respectively. The share-based compensation expense recognized included expense for stock options, RSUs and our employee stock purchase plan purchase rights. In 2023, non-cash expense of $5.1 million was recorded related to the one-time recognition of stock option and RSU expense in order to match the grant expense to the service period for the role in which the grants were originally made following the transition of the Company's then CEO to Chairman of the Board of Directors. Additionally, the vesting of these awards remains contingent on future service.

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, 2023 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, employee retention credit, investments, share-based compensation and utilization of net operating loss carryforwards 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

The Company's revenues generally consist of (i) contract and grant revenue—revenue generated under federal and private foundation grants and contracts, (ii) licensing revenue—revenue related to non-refundable upfront fees, royalties and milestone payments earned under license agreements (iii) royalty revenue—revenue related to sales of TEMBEXA made by Emergent after the Asset Sale, and (iv) procurement revenue—revenue related to sales of TEMBEXA prior to the Asset Sale. 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.

Emergent BioSolutions, Inc.

On September 26, 2022, the Company closed the previously disclosed Asset Sale with Emergent. Emergent paid the Company an upfront cash payment of approximately $238 million upon closing. In addition, pursuant to the Asset Purchase Agreement,

the Company is eligible to receive from Emergent: (i) up to an aggregate of approximately $124 million in milestone payments payable upon the exercise of the options under the BARDA Agreement; (ii) royalty payments equal to 15% of the gross profits from the sales of TEMBEXA made outside of the United States; (iii) royalty payments equal to 20% of the gross profits from the sales of TEMBEXA made in the United States in excess of 1.7 million treatment courses; and (iv) up to an additional $12.5 million upon the achievement of certain other developmental milestones.

The BARDA Agreement was novated to Emergent in December 2022. Under Asset Purchase Agreement, the Company recognized approximately $0.2 million and $0.5 million of contract revenue for support provided for the twelve months ended December 31, 2023 and 2022, respectively.

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) 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. Under the BARDA contract, we recognized contract revenue of $1.6 million during the twelve months ended December 31, 2021.

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. At December 31, 2023, the Company had a deferred revenue balance of $0.1 million related to these grants. Additionally, for the twelve months ended December 31, 2023 and 2022, the Company recognized $30,000 and $0.5 million, respectively, of grant revenue related to these grants.

Ohara Agreement

In 2019, Oncoceutics, Inc., a Delaware corporation (Oncoceutics) which was subsequently acquired by the Company in January 2021, 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 double-digit tiered royalties based on the aggregate annual net sales of all products, as defined in the agreement, in Japan. For the twelve months ended December 31, 2023 and 2022, the Company recognized approximately $58,000 and $0.5 million, respectively, of license revenue related to this agreement.

TEMBEXA Procurement Agreements Revenue and Royalty Revenue

In June 2022, the Company entered into a Supply Agreement (the Supply Agreement) with a third-party outside of North America (the Purchaser), pursuant to which the Company was responsible for supplying to the Purchaser, and the Purchaser was responsible for purchasing from the Company, TEMBEXA treatment courses for use in a jurisdiction outside of the United States. Under the terms of the Supply Agreement, the Purchaser paid the Company an aggregate purchase price of approximately $9.3 million, in two equal installments in June 2022 and July 2022. The Company recognized $9.3 million of procurement revenue under the Supply Agreement for the twelve months ended December 31, 2022.

Additionally, in June 2022, the Public Health Agency of Canada (PHAC) awarded a Contract (the PHAC Contract) to the Company, pursuant to which PHAC agreed to purchase up to approximately $25.3 million (CAD $33.0 million) of TEMBEXA treatment courses for use in Canada. Substantially all of the procurement was delivered and accepted by PHAC in July 2022, completing the performance obligation for those shipments and resulting in $22.6 million of procurement revenue for the twelve months ended December 31, 2022. PHAC assigned the PHAC Contract to Emergent in November 2022. The remaining deliveries of treatment courses were delivered by Emergent and were subject to the royalty terms of the Asset Purchase

Agreement applicable to gross profits outside the United States. The Company recognized approximately $0.4 million of royalty revenue in the twelve months ended December 31, 2022.

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, 2023, 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

The Company considers 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. The Company begins capitalization of these inventory related costs once regulatory approval is obtained. The Company primarily uses actual costs to determine its cost basis for inventories.

On May 15, 2022, we entered into an Asset Purchase Agreement (the Asset Purchase Agreement) with an affiliate of Emergent BioSolutions Inc. (Emergent BioSolutions) for the sale of our exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale). On September 26, 2022, we closed the Asset Sale with Emergent Biodefense Operations Lansing LLC (Emergent), an affiliate of Emergent BioSolutions.

Prior to the sale of TEMBEXA to Emergent, the Company's inventory consisted of TEMBEXA, which was being manufactured for the treatment of smallpox for potential delivery to the Strategic National Stockpile (SNS) for the U.S. government and to other government agencies. TEMBEXA was approved by the FDA on June 4, 2021, at which time the Company 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.

The Company valued its inventories at the lower of cost or estimated net realizable value. The Company determined the cost of its inventories, which included amounts related to materials, manufacturing costs, shipping and handling costs on a first-in, first-out (FIFO) basis. Work-in-process included all inventory costs prior to packaging and labelling, including raw material,

active product ingredient, and drug product. Finished goods included packaged and labelled products. Title to all inventory was transferred to Emergent upon the close of the Asset Sale.

Employee Retention Credit

Under the provisions of the extension of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) passed by the United States Congress and signed by the President, the Company is eligible for a refundable employee retention credit subject to certain criteria. The Company recognized a $2.0 million employee retention credit during the twelve months ended December 31, 2022 related to labor costs recognized during 2020 and 2021, which is recorded in prepaid expenses and other current assets. For the twelve months ended December 31, 2022, $1.5 million is recorded as a reduction to research and development expenses and $0.5 million is recorded as a reduction to general and administrative expenses. The Company has filed for refunds of the employee retention credits and as of the date of this Annual Report on Form 10-K, it has received $27,000 of refunds and cannot reasonably estimate when it will receive any or all of the remaining refunds.

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,		
	2023	**2022**	**2021**
Income Statement Classification:			
Research and development expense	$ 7,092	$ 8,267	$ 6,611
General and administrative expense	10,365	7,018	5,649
Total stock-based compensation expense	$ 17,457	$ 15,285	$ 12,260

In 2023, non-cash expense of $5.1 million was recorded related to the one-time recognition of stock option and RSU expense in order to match the grant expense to the service period for the role in which the grants were originally made following the transition of the Company's then CEO to Chairman of the Board of Directors. Additionally, the vesting of these awards remains contingent on future service.

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, 2023, 2022, and 2021 are set forth below:

Stock Options

	Years Ended December 31,		
	2023	2022	2021
Expected volatility	83.20 %	74.27 %	95.84 %
Expected term (in years)	5.7	6.0	6.0
Weighted-average risk-free interest rate	3.87 %	1.91 %	0.71 %
Expected dividend yield	— %	— %	— %
Weighted-average fair value per option	$ 1.13	$ 3.33	$ 6.67

Employee Stock Purchase Plan

	Years Ended December 31,		
	2023	2022	2021
Expected volatility	94.64 %	104.88 %	97.54 %
Expected term (in years)	1.50	1.28	0.71
Weighted-average risk-free interest rate	4.63 %	2.63 %	0.25 %
Expected dividend yield	— %	— %	— %
Weighted-average option value per share	$ 0.75	$ 1.97	$ 6.55

Utilization of Net Operating Loss Carryforwards

As of December 31, 2023, we had net operating loss carryforwards for federal and state tax purposes of approximately $423.2 million and $416.0 million, respectively. As of December 31, 2022, we had net operating loss carryforwards for federal and state tax purposes of approximately $394.8 million and $394.4 million, respectively. In addition, we had tax credit carryforwards for federal tax purposes of approximately $29.9 million as of December 31, 2023. 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 change, by value, in our equity ownership over a three-year period, 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 may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, under the Tax Act, as amended by the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017 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 or the CARES 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, 2023 and December 31, 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and December 31, 2022, together with the changes in those items in dollars and percentages (in thousands, except percentages):

	Years Ended December 31,		Dollar Change	% Change
	2023	2022	Increase/(Decrease)	
Revenues:				
Procurement revenue	$ —	$ 31,971	$ (31,971)	(100.0)%
Contract and grant revenue	275	942	(667)	(70.8)%
Licensing revenue	49	536	(487)	(90.9)
Royalty revenue	—	375	(375)	(100.0)
Total revenues	324	33,824	(33,500)	(99.0)%
Cost of goods sold	—	447	(447)	(100.0)%
Gross Profit	324	33,377	(33,053)	(99.0)%
Operating expenses:				
Research and development	68,788	71,631	(2,843)	(4.0)%
General and administrative	24,601	22,132	2,469	11.2 %
Total operating expenses	93,389	93,763	(374)	(0.4)%
Loss from operations	(93,065)	(60,386)	(32,679)	54.1 %
Other income:				
Interest income and other, net	10,970	2,919	8,051	275.8 %
Gain on sale of business, net	—	229,670	(229,670)	(100.0)%
(Loss) income before income taxes	(82,095)	172,203	(254,298)	(147.7)%
Income tax expense	—	36	(36)	(100.0)%
Net (loss) income	$ (82,095)	$ 172,167	$ (254,262)	(147.7)%

Procurement, Contract, Licensing and Royalty Revenue

For the year ended December 31, 2023, total revenues decreased to $0.3 million compared to $33.8 million for the year ended December 31, 2022. The decrease of $33.5 million, or 99.0%, was primarily related to the 2022 deliveries under the international TEMBEXA procurement agreements.

Cost of Goods Sold

For the year ended December 31, 2023, we did not record any cost of goods sold as compared to December 31, 2022 where we recorded $0.4 million of cost of goods sold attributable to the international TEMBEXA procurement deliveries and the write-off of inventory deemed nonsalable.

Research and Development Expenses

For the year ended December 31, 2023, our research and development expenses decreased to $68.8 million compared to $71.6 million for the year ended December 31, 2022. The decrease of $2.8 million, or 4.0%, was primarily related to the following:

- a decrease of $4.0 million in DSTAT development costs related to the discontinuation of the DSTAT program;
- a decrease of $3.4 in compensation expenses, of which $1.2 million is related to non-cash stock compensation expense;
- a decrease of $1.9 million for the development of our other pipeline products, ONC206, ONC212, and CMX521;
- a decrease of $0.7 million in TEMBEXA expenses as the asset was sold to Emergent in 2022; offset by
- an increase of $6.8 million related to ONC201 research and development expenses and start-up expenses related to the ACTION Phase 3 study of ONC201 in patients who harbor the H3 K27M-mutation.

General and Administrative Expenses

For the year ended December 31, 2023, our general and administrative expenses increased to $24.6 million compared to $22.1 million for the year ended December 31, 2022. The increase of $2.5 million, or 11.2%, was primarily related to the following:

- an increase of $3.4 million in non-cash stock compensation expenses primarily related to the one-time recognition of stock option and RSU expense in order to match the grant expense to the service period for the role in which the grants were originally made following the transition of the Company's then-CEO to Chairman of the Board of Directors; offset by
- a decrease of $0.9 million in legal and other operational expenses primarily related to the Asset Sale with Emergent and international TEMBEXA procurement agreements secured in 2022.

Interest Income and Other, Net

For the year ended December 31, 2023, our interest income and other, net was $11.0 million compared to interest income of $2.9 million for the year ended December 31, 2022. The increase of $8.1 million was largely attributable to the increased cash balance from proceeds received during 2022 related to the Asset Sale with Emergent and international TEMBEXA procurement agreements.

Gain on Sale of Business, Net

For the year ended December 31, 2022, we recorded a net gain of $229.7 million related to the sale of the exclusive worldwide rights to brincidofovir, including TEMBEXA and specified related assets to Emergent.

Comparison of the Years ended December 31, 2022 and December 31, 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and December 31, 2021, together with the changes in those items in dollars and percentages (in thousands, except for percentages):

	Years Ended December 31,		Dollar Change	% Change
	2022	2021	Increase/(Decrease)	
Revenues:				
Procurement revenue	$ 31,971	$ —	$ 31,971	*
Contract and grant revenue	942	1,928	(986)	(51.1)%
Licensing revenue	536	51	485	951.0
Royalty revenue	375	—	375	*
Total revenues	33,824	1,979	31,845	1,609.1 %
Cost of goods sold	447	—	447	*
Gross Profit	33,377	1,979	31,398	1,586.6 %
Operating expenses:				
Research and development	71,631	73,817	(2,186)	(3.0)%
General and administrative	22,132	18,672	3,460	18.5 %
Acquired in-process research and development	—	82,890	(82,890)	(100.0)%
Total operating expenses	93,763	175,379	(81,616)	(46.5)%
Loss from operations	(60,386)	(173,400)	113,014	(65.2)%
Other income:				
Interest income and other, net	2,919	164	2,755	1,679.9 %
Gain on sale of business, net	229,670	—	229,670	*
(Loss) income before income taxes	172,203	(173,236)	345,439	(199.4)%
Income tax expense	36	—	36	*
Net (loss) income	$ 172,167	$ (173,236)	$ 345,403	(199.4)%

***** Not meaningful or not calculable

Procurement, Contract, Licensing and Royalty Revenue

For the year ended December 31, 2022, total revenues increased to $33.8 million compared to $2.0 million for the year ended December 31, 2021. The increase of $31.8 million, or 1,609.1%, was primarily related to the deliveries under the international TEMBEXA procurement agreements.

Cost of Goods Sold

For the year ended December 31, 2022, cost of goods sold increased to $0.4 million and for the year ended December 31, 2021 we did not record any cost of goods sold. The increase of $0.4 million is attributable to the international TEMBEXA procurement deliveries and the write-off of inventory deemed nonsalable.

Research and Development Expenses

For the year ended December 31, 2022, our research and development expenses decreased to $71.6 million compared to $73.8 million for the year ended December 31, 2021. The increase of $2.2 million, or 3.0%, was primarily related to the following:

- an increase of $20.3 million related to ONC201 research and development expenses and start-up expenses related to the ACTION Phase 3 study of ONC201 in patients who harbor the H3 K27M-mutation;
- an increase of $3.0 million in compensation expenses, of which $1.7 million is related to non-cash stock compensation expense and $0.8 million relates to the accrual of severance related expenses;
- an increase of $2.5 million for the development of our other pipeline products, ONC206, ONC212, and CMX521; offset by
- a decrease of $20.0 million related to the success milestone payment to Oncoceutics shareholders upon the achievement of a 20% ORR by BICR of ONC201 paid out in 2021;
- a decrease of $4.8 million in DSTAT development costs related to the discontinuation of the DSTAT program; and
- a decrease of $2.5 million in TEMBEXA expense.

General and Administrative Expenses

For the year ended December 31, 2022, our general and administrative expenses increased to $22.1 million compared to $18.7 million for the year ended December 31, 2021. The increase of $3.5 million, or 18.5%, was primarily related to the following:

- an increase of $1.7 million in compensation expenses, of which $1.4 million is related to non-cash stock compensation expense; and
- an increase of $1.8 million primarily related to legal, and consulting expenses, related to the TEMBEXA transactions.

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, 2022, our interest income and other, net was $2.9 million compared to interest income of $0.2 million for the year ended December 31, 2021. The decrease of $2.8 million was largely attributable to an increase in interest rates on the increased cash balance from proceeds received during 2022 related to the Asset Sale with Emergent and international TEMBEXA procurement agreements.

Gain on Sale of Business, Net

For the year ended December 31, 2022, we recorded a net gain of $229.7 million related to the sale of the exclusive worldwide rights to brincidofovir, including TEMBEXA and specified related assets to Emergent.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2023, we had capital available to fund operations of approximately $204.5 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, 2023, we had an accumulated deficit of $795.5 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 SM (Prior 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. As of August 9, 2023, the Form S-3 shelf registration statement that registered the shares of common stock available for sale under the Prior Jefferies Sales Agreement expired at the end of its three-year term, and is no longer available for use. We have not sold any shares of our common stock under the Prior Jefferies Sales Agreement. On February 29, 2024, we terminated the Prior Jefferies Sales Agreement with Jefferies LLC in connection with a new sales agreement by and between Jefferies and us, as discussed below.

On May 6, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC (the 2021 Shelf Registration Statement), which was subsequently amended in March 2022 to convert it to a non-automatic shelf registration statement that we are eligible to use. The amendment to the 2021 Shelf Registration Statement to convert to a non-automatic shelf registration statement. This registration statement enables us to offer for sale, from time to time, in one or more offerings, up to $250 million in the aggregate, of common stock, preferred stock, debt securities, warrants, rights and/or units, and will remain in effect for up to three years from the date it initially became effective. We have not sold any shares of our securities under the 2021 Shelf Registration Statement.

On January 31, 2022, we entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank, now a division of First-Citizens Bank & Trust Company, 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. We have no obligation to draw down any amount under the Credit Facility, and have not drawn down any amount as of December 31, 2023. In September 2022, in connection with the Asset Sale, the Lender and the Company agreed to suspend the availability of future advances under the Loan Agreement until such time the parties mutually agree to amend the Loan Agreement to, among other things, adjust the borrowing base and reset the covenants. On November 21, 2023 the Loan Agreement was amended to, among other things, reinstate the availability of advances.

On February 29, 2024, we entered into an Open Market Sale Agreement SM (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. On the same day, we will file a shelf registration statement on Form S-3 with the SEC, which contains a base prospectus, covering up to a total aggregate offering price of $250 million of our common stock, preferred stock, debt securities and warrants to purchase any of such securities, and a sales agreement prospectus, covering the offering, issuance and sale of up to a maximum aggregate offering price of $75 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. The $75 million of shares that may be issued and sold from time to time under the Jefferies Sales Agreement is included in the $250 million of securities that may be offered, issued and sold by us pursuant to our shelf registration statement.

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:	**2023**	**2022**	**2021**
Net cash used in operating activities	$ (69,088)	$ (46,867)	$ (99,930)
Net cash provided by (used in) investing activities	70,599	70,037	(44,091)
Net cash provided by (used in) financing activities	308	(12,725)	112,429
Net increase (decrease) in cash and cash equivalents	$ 1,819	$ 10,445	$ (31,592)

Operating Activities

Net cash used in operating activities of $69.1 million for the year ended December 31, 2023 was primarily the result of our net loss of $82.1 million offset by the change in operating asset and liabilities and add-back of non-cash adjustments. The change in operating assets and liabilities includes a decrease in prepaid expenses and other assets of $3.4 million and a decrease in accounts receivable of $1.0 million, offset by a decrease in accounts payable and accrued liabilities of $2.1 million. Non-cash adjustments included an add-back of $17.5 million for stock-based compensation, $0.2 million for amortization of debt issuance costs and $0.1 million of depreciation of property and equipment, offset by $7.0 million of amortization of discount/premium on investments.

Net cash used in operating activities of $46.9 million for the year ended December 31, 2022 was primarily the result of our net income of $172.2 million 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 an increase in prepaid expenses and other assets of $5.4 million, an increase in inventories of $2.5 million and an increase of $1.0 million in accounts receivable, offset by a decrease in accounts payable and accrued liabilities of $5.5 million. Non-cash adjustments included an adjustment of $229.7 million for the gain on the sale of TEMBEXA and $1.6 million of amortization of discount/premium on investments, offset by the add-backs of $15.3 million for stock-based compensation, $0.2 million for amortization of debt issuance costs and $0.1 million of depreciation of property and equipment.

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 assets and liabilities and the add-back of non-cash expenses. The change in operating assets and liabilities includes an 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.

Investing Activities

Net cash provided by investing activities of $70.6 million during the year ended December 31, 2023 was primarily the result of the maturity of $199.2 million in short-term investments, offset by purchases of $90.0 million of short-term investments and the purchase of $38.5 million of long-term investments. Net cash provided by investing activities of $70.0 million during the year ended December 31, 2022 was primarily the result of $234.0 million of proceeds from the sale of TEMBEXA, the maturity of $69.5 million in short-term investments and the sale of $7.7 million of short-term investments, offset by the purchases of $183.2 million of short-term investments and the purchase of $57.8 million of long-term investments. Net cash used 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.

Financing Activities

Net cash provided by financing activities of $0.3 million for the year ended December 31, 2023 was primarily the result of $0.5 million from purchases under the ESPP, partially offset by the payment of $0.2 million of debt issuance costs. Net cash used by financing activities of $12.7 million for the year ended December 31, 2022 was primarily the result of the $14.0 million payment of the note payable related to the Oncoceutics acquisition and the payment of $0.2 million of debt issuance costs, partially offset by $1.5 million from the exercise of stock options and purchases under the ESPP. 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.

Future Funding Requirements

To date, we have generated modest, non-recurring revenue from product sales. Since inception, other than 2022 which included product sales, all of our revenue to date derived from government grants and a contract and the receipt of up-front proceeds under our collaboration and license agreements.

We do not know when, or if, we will generate any additional revenue from product sales or receive royalties from our partners' product sales. We do not expect to generate significant revenue from product sales unless and until we commercialize ONC201 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.

MATERIAL CASH REQUIREMENTS

Leases. See Note 4 of Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K for information, including the future operating lease minimum payments.

In addition to the amounts set forth 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, 2023, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. In connection with the development and commercialization of ONC201, ONC206 and ONC212, 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.
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. 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.

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, 2023 or 2022.

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, 2023 and 2022, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

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 $7.6 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	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
February 29, 2024

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

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,661	$ 25,842
Short-term investments, available-for-sale	155,174	191,492
Accounts receivable	4	1,040
Prepaid expenses and other current assets	6,271	9,764
Total current assets	189,110	228,138
Long-term investments	21,657	48,626
Property and equipment, net of accumulated depreciation	224	227
Operating lease right-of-use assets	1,482	1,964
Other long-term assets	301	386
Total assets	$ 212,774	$ 279,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,851	$ 3,034
Accrued liabilities	15,592	17,381
Total current liabilities	18,443	20,415
Line of credit commitment fee	125	250
Lease-related obligations	1,177	1,819
Total liabilities	19,745	22,484
Stockholders' equity:		
Preferred stock, $ 0.001 par value, 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock, $ 0.001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 88,929,300 and 88,054,127 shares issued and outstanding at December 31, 2023 and 2022, respectively	89	88
Additional paid-in capital	988,457	970,535
Accumulated other comprehensive gain (loss), net	7	(337)
Accumulated deficit	(795,524)	(713,429)
Total stockholders' equity	193,029	256,857
Total liabilities and stockholders' equity	$ 212,774	$ 279,341

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

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Revenues:			
Procurement revenue	$ —	$ 31,971	$ —
Contract and grant revenue	275	942	1,928
Licensing revenue	49	536	51
Royalty revenue	—	375	—
Total revenues	324	33,824	1,979
Cost of goods sold	—	447	—
Gross Profit	324	33,377	1,979
Operating expenses:			
Research and development	68,788	71,631	73,817
General and administrative	24,601	22,132	18,672
Acquired in-process research and development	—	—	82,890
Total operating expenses	93,389	93,763	175,379
Loss from operations	(93,065)	(60,386)	(173,400)
Other income:			
Interest income and other, net	10,970	2,919	164
Gain on sale of business, net	—	229,670	—
(Loss) income before income taxes	(82,095)	172,203	(173,236)
Income tax expense	—	36	—
Net (loss) income	(82,095)	172,167	(173,236)
Other comprehensive income (loss):			
Unrealized gain (loss) on debt investments, net	344	(316)	(21)
Comprehensive (loss) income	$ (81,751)	$ 171,851	$ (173,257)
Per share information:			
Net (loss) income, basic	$ (0.93)	$ 1.97	$ (2.04)
Net (loss) income, diluted	$ (0.93)	$ 1.94	$ (2.04)
Weighted-average shares outstanding, basic	88,604,026	87,555,110	84,930,255
Weighted-average shares outstanding, diluted	88,604,026	88,776,147	84,930,255

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

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

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
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
Share-based compensation	—	—	15,285	—	—	$ 15,285
Exercise of stock options	271,079	—	608	—	—	$ 608
Employee stock purchase plan purchases	535,255	1	860	—	—	$ 861
RSU stock issuance	363,527	—	—	—	—	$ —
Comprehensive income (loss):						
Unrealized loss on investments, net	—	—	—	(316)	—	$ (316)
Net income	—	—	—	—	172,167	$ 172,167
Total comprehensive income						171,851
Balance, December 31, 2022	88,054,127	$ 88	$ 970,535	$ (337)	$ (713,429)	$ 256,857
Share-based compensation	—	—	17,457	—	—	$ 17,457
Employee stock purchase plan purchases	429,233	1	465	—	—	$ 466
RSU stock issuance	445,940	—	—	—	—	$ —
Comprehensive income (loss):						
Unrealized gain on investments, net	—	—	—	344	—	$ 344
Net loss	—	—	—	—	(82,095)	$ (82,095)
Total comprehensive loss						$ (81,751)
Balance, December 31, 2023	88,929,300	$ 89	$ 988,457	$ 7	$ (795,524)	$ 193,029

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,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net income (loss)	$ (82,095)	$ 172,167	$ (173,236)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation of property and equipment	91	98	167
Amortization of debt issuance costs	183	233	—
Amortization of discount/premium on investments	(7,049)	(1,566)	846
Share-based compensation	17,457	15,285	12,260
Fair value of common stock issued related to asset acquisition	—	—	43,445
Note payable related to asset acquisition	—	—	14,000
Gain on sale of TEMBEXA	—	(229,670)	—
Gain on sale of equipment	(8)	—	—
Gain on sale of investments	—	(1)	(2)
Lease-related amortization	(90)	9	301
Changes in operating assets and liabilities:			
Accounts receivable	1,036	(1,040)	340
Inventories	—	(2,467)	(2,760)
Prepaid expenses and other assets	3,440	(5,419)	(2,352)
Accounts payable and accrued liabilities	(2,053)	5,504	7,061
Net cash used in operating activities	(69,088)	(46,867)	(99,930)
Cash flows from investing activities:			
Purchases of property and equipment	(89)	(71)	(207)
Purchases of short-term investments	(89,982)	(183,245)	(105,355)
Purchases of long-term investments	(38,518)	(57,810)	(9,594)
Proceeds from sales of short-term investments	—	7,699	4,207
Proceeds from maturities of short-term investments	199,180	69,480	66,858
Proceeds from sale of TEMBEXA	—	233,984	—
Proceeds from sale of property and equipment	8	—	—
Net cash provided by (used in) investing activities	70,599	70,037	(44,091)
Cash flows from financing activities:			
Proceeds from exercise of stock options	—	608	3,831
Proceeds from employee stock purchase plan	465	860	755
Proceeds from issuance of common stock, net of commissions	—	—	107,843
Payments of debt issuance costs	(157)	(193)	—
Payment of note payable	—	(14,000)	—
Net cash provided by (used in) financing activities	308	(12,725)	112,429
Net increase (decrease) in cash and cash equivalents	1,819	10,445	(31,592)
Cash and cash equivalents:			
Beginning of period	25,842	15,397	46,989
End of period	$ 27,661	$ 25,842	$ 15,397

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

CHIMERIX, INC.
NOTES TO 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. The Company is focused on developing imipridones as a potential new class of selective cancer therapies. The most advanced imipridone is dordaviprone (ONC201) which is in clinical-stage development for H3 K27M-mutant diffuse glioma as its lead indication. In addition, a second-generation imipridone (ONC206) is currently in dose escalating clinical trials for adult and pediatric patients with primary central nervous system tumors.

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.

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, 2023, no realized gains or losses 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, and long-term investments. 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

Accounts receivable at December 31, 2023 consisted of amounts billed under the Company's transition services agreement with Emergent. 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.

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, 2023			
	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	$ 24,102	$ 24,102	$ —	$ —
Total cash equivalents	24,102	24,102	—	—
Short-term investments				
U.S. Treasury securities	99,779	40,336	59,443	—
Commercial paper	44,319	—	44,319	—
Corporate bonds	11,076	—	11,076	—
Total short-term investments	155,174	40,336	114,838	—
Long-term investments				
U.S. Treasury securities	21,657	3,975	17,682	—
Total long-term investments	21,657	3,975	17,682	—
Total assets	$ 200,933	$ 68,413	$ 132,520	$ —

	Fair Value Measurements December 31, 2022			
	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	$ 17,826	$ 17,826	$ —	$ —
Commercial paper	4,998	—	4,998	—
Total cash equivalents	22,824	17,826	4,998	—
Short-term investments				
U.S. Treasury securities	38,094	25,271	12,823	—
Commercial paper	127,517	—	127,517	—
Corporate bonds	25,881	—	25,881	—
Total short-term investments	191,492	25,271	166,221	—
Long-term investments				
U.S. Treasury securities	48,626	11,685	36,941	—
Total long-term investments	48,626	11,685	36,941	—
Total assets	$ 262,942	$ 54,782	$ 208,160	$ —

Inventories

The Company considers 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. The Company begins capitalization of these inventory related costs once regulatory approval is obtained. The Company primarily uses actual costs to determine its cost basis for inventories.

On May 15, 2022, we entered into an Asset Purchase Agreement (the Asset Purchase Agreement) with an affiliate of Emergent BioSolutions Inc. (Emergent BioSolutions) for the sale of our exclusive worldwide rights to brincidofovir, including

TEMBEXA® and specified related assets (the Asset Sale). On September 26, 2022, we closed the Asset Sale with Emergent Biodefense Operations Lansing LLC (Emergent), an affiliate of Emergent BioSolutions.

Prior to the sale of TEMBEXA to Emergent, the Company's inventory consisted of TEMBEXA, which was being manufactured for the treatment of smallpox for potential delivery to the Strategic National Stockpile (SNS) for the U.S. government and to other government agencies. TEMBEXA was approved by the FDA on June 4, 2021, at which time the Company 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.

The Company valued its inventories at the lower of cost or estimated net realizable value. The Company determined the cost of its inventories, which included amounts related to materials, manufacturing costs, shipping and handling costs on a first-in, first-out (FIFO) basis. Work-in-process included all inventory costs prior to packaging and labelling, including raw material, active product ingredient, and drug product. Finished goods included packaged and labelled products. Title to all inventory was transferred to Emergent upon the close of the Asset Sale.

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	**2022**
Prepaid research and development expenses	$ 1,815	$ 3,399
Interest receivable	1,136	643
Prepaid insurance	431	564
Other prepaid expenses and current assets	2,889	5,158
Total prepaid expenses and other current assets	$ 6,271	$ 9,764

Employee Retention Credit

Under the provisions of the extension of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) passed by the United States Congress and signed by the President, the Company is eligible for a refundable employee retention credit subject to certain criteria. The Company recognized a $ 2.0 million employee retention credit during twelve months ended December 31, 2022 related to labor costs recognized during 2020 and 2021, which is recorded in prepaid expenses and other current assets. For the twelve months ended December 31, 2022, $ 1.5 million is recorded as a reduction to research and development expenses and $ 0.5 million is recorded as a reduction to general and administrative expenses. The Company has filed for refunds of the employee retention credits and as of the date of this Annual Report on Form 10-K, it has received $ 27,000 of refunds and cannot reasonably estimate when it will receive any or all of the remaining refunds.

Deferred Loan Costs

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 December 31, 2023.

In September 2022, in connection with the Asset Sale, the Lender and the Company agreed to suspend the availability of future advances under the Loan Agreement until such time the parties mutually agree to amend the Loan Agreement to, among other things, adjust the borrowing base and reset the covenants.

On November 21, 2023, the Company entered into the First Amendment to the Loan Agreement, which extended the term to September 30, 2026 and increased the unused line fee to 0.35 % per annum on the unused portion of the Credit Facility, payable quarterly in arrears.

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 0.35 % 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. As of December 31, 2023, the Company has recorded current deferred loan costs of $ 0.1 million in prepaid expenses and other current assets and non-current deferred loan costs of $ 0.2 million in other long-term assets on the Consolidated Balance Sheets. As of December 31, 2023, the Company has recorded a current loan fee liability of $ 0.2 million in accrued liabilities and a non-current loan fee liability of $ 0.1 million in line of credit commitment fee on the Consolidated Balance Sheets.

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, 2023 and 2022, 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,	
	2023	**2022**
Accrued compensation	$ 5,123	$ 6,438
Accrued research and development expenses	7,623	6,691
Other accrued liabilities	2,846	4,252
Total accrued liabilities	$ 15,592	$ 17,381

Revenue Recognition

Policy

The Company's revenues generally consist of (i) contract and grant revenue—revenue generated under federal and private foundation grants and contracts, (ii) licensing revenue—revenue related to non-refundable upfront fees, royalties and milestone payments earned under license agreements (iii) royalty revenue—revenue related to sales of TEMBEXA made by Emergent after the Asset Sale, and (iv) procurement revenue—revenue related to sales of TEMBEXA prior to the Asset Sale. 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.

Emergent BioSolutions, Inc.

On September 26, 2022, the Company completed the Asset Sale to Emergent of the Company's exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale). Emergent paid the Company an upfront cash payment of approximately $ 238 million upon the closing of the Asset Sale. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from Emergent: (i) up to an aggregate of approximately $ 124 million in milestone payments payable upon the exercise of the options under the BARDA Agreement for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA to the U.S. government; (ii) royalty payments equal to 15 % of the gross profits from the sales of TEMBEXA made outside of the United States; (iii) royalty payments equal to 20 % of the gross profits from the sales of TEMBEXA made in the United States in excess of 1.7 million treatment courses; and (iv) up to an additional $ 12.5 million upon the achievement of certain other developmental milestones.

The BARDA Agreement was novated to Emergent in December 2022. Under Asset Purchase Agreement, the Company recognized approximately $ 0.2 million and $ 0.5 million of contract revenue for support provided for the twelve months ended December 31, 2023 and 2022, respectively.

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) 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. Under the BARDA contract, we recognized contract revenue of $ 1.6 million during the twelve months ended December 31, 2021.

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. At December 31, 2023, the Company had a deferred revenue balance of $ 0.1 million

related to these grants. Additionally, for the twelve months ended December 31, 2023, 2022 and 2021, the Company recognized $ 30,000 and $ 0.5 million and $ 0.4 million, respectively, of grant revenue related to these grants.

Ohara Agreement

In 2019, Oncoceutics, Inc., a Delaware corporation (Oncoceutics) which was subsequently acquired by the Company in January 2021, 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 double-digit tiered royalties based on the aggregate annual net sales of all products, as defined in the agreement, in Japan. For the twelve months ended December 31, 2023, 2022 and 2021, the Company recognized approximately $ 0.1 million, $ 0.5 million and $ 47,000 , respectively, of license revenue related to this agreement.

TEMBEXA Procurement Agreements Revenue and Royalty Revenue

In June 2022, the Company entered into the Supply Agreement and the PHAC Contract (as defined in Note 6 below), pursuant to which the Company was responsible for supplying TEMBEXA (brincidofovir) treatment courses for use outside of the United States. There are no material performance obligations outside of delivery in the agreements, therefore revenue related to these procurement agreements was recognized when the delivery performance obligation was satisfied. Revenue was recognized based on price per treatment course as outlined in the agreements. For the twelve months ended December 31, 2022, the Company recognized $ 32.0 million of procurement revenue related to these agreements.

The PHAC Contract was assigned to Emergent in November 2022. The remaining deliveries of treatment courses were delivered by Emergent and are subject to the royalty terms of the Asset Purchase Agreement applicable to gross profits outside the United States. The Company recognized approximately $ 0.4 million of royalty revenue in the twelve months ended December 31, 2022.

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, 2023, 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.

Gain on Sale of Business, Net

Emergent Biodefense Operations Lansing LLC

The previously mentioned sale of TEMBEXA constitutes a significant disposition of a business, however, the Company determined the disposition does not represent a strategic shift, and accordingly, the Company has not accounted for the disposition as a discontinued operation. The Company recorded a $ 229.7 million net gain on sale of business in other income (loss) on the Consolidated Statement of Operations and Comprehensive Income (Loss) for the twelve months ended December 31, 2022.

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, 2023, with the exception of the fiscal year ended December 31, 2022, and therefore has not recorded any current provision for income taxes in the current year. For the year ended December 31, 2022, the Company recorded net income and incurred a small amount of state income tax expense. As such the Company recorded a provision for current state income taxes for the year ended December 31, 2022.

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, 2023, 2022 and 2021, 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, 2023, 2022 and 2021, the Company recognized expenses for matching contributions of $ 0.5 million, $ 0.5 million and $ 0.4 million, respectively.

Basic and Dilutive Net Loss Per Share of Common Stock

Basic net income (loss) per share of common stock is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of non-vested restricted stock, stock options, and employee stock purchase plan purchase rights. Diluted net income (loss) per share of common stock is computed by dividing net income (loss) by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of 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. For the twelve months ended December 31, 2022, the diluted per-share computations reflect the number of additional common stock outstanding that would have been outstanding if the potentially dilutive common stock had been issued. 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 for the twelve months ended December 31, 2023 and 2021.

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 1,322,712 , and 4,672,859 , for the years ended December 31, 2023 and 2021, respectively.

Segments

The Company operates in only one segment, pharmaceuticals.

Impact of Recently Adopted 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 adopted ASU 2016-03 as of January 1, 2023. Given the nature of the Company's receivables and investment portfolio, adoption of this standard had no impact on the Company's financial position, results of operations or cash flows.

Note 2. Investments

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

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 11,079	$ 4	$ (7)	$ 11,076
Commercial paper	44,271	52	(4)	44,319
U.S. Treasury securities	121,474	126	(164)	121,436
Total investments	$ 176,824	$ 182	$ (175)	$ 176,831

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 25,906	$ 4	$ (29)	$ 25,881
Commercial paper	127,657	36	(176)	127,517
U.S. Treasury securities	86,892	7	(179)	86,720
Total investments	$ 240,455	$ 47	$ (384)	$ 240,118

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, 2023					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 6,365	$ (7)	$ —	$ —	$ 6,365	$ (7)
Commercial paper	5,464	(4)	—	—	5,464	(4)
U.S. Treasury securities	64,531	(120)	14,937	(44)	79,468	(164)
Total	$ 76,360	$ (131)	$ 14,937	$ (44)	$ 91,297	$ (175)
Number of securities with unrealized losses		24		4		28

	December 31, 2022					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 22,905	$ (29)	$ —	$ —	$ 22,905	$ (29)
Commercial paper	88,860	(176)	—	—	88,860	(176)
U.S. Treasury securities	67,489	(179)	—	—	67,489	(179)
Total	$ 179,254	$ (384)	$ —	$ —	$ 179,254	$ (384)
Number of securities with unrealized losses		55		—		55

The Company invests in high credit quality investments in accordance with its investment policy, which is designed to minimize the possibility of loss. The objective of the Company's investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. The Company places its excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of its credit exposure. In accordance with its policy, the Company is able to invest in marketable debt securities that may consist of U.S. Government and government agency securities, money market and mutual fund investments, certificates of deposits, municipal and corporate notes and bonds, and commercial paper, among others. The Company's investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of two years and requires an average portfolio maturity of no more than 12 months. Some of the securities in which the Company invests may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe it has a material exposure to interest rate risk arising from its investments. Generally, the Company's investments are not collateralized. The Company has not realized any significant losses from its investments.

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive loss, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below 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 cost basis. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Unrealized gains and losses on debt investments are recorded to unrealized gain (loss) on debt investments, net in the Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses on debt investments are recorded based on specific identification to interest income and other, net in the Consolidated Statements of Operations and Comprehensive Loss. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current investments. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term investments. At December 31, 2023, the Company believes that the cost of its investments is recoverable in all

material respects. The Company recognizes interest income on an accrual basis in interest income in the Consolidated Statements of Operations and Comprehensive Loss.

The following table summarizes the scheduled maturity for the Company's debt investments at December 31, 2023 (in thousands):

	December 31, 2023
Maturing in one year or less	$ 155,174
Maturing after one year through two years	21,657
Total debt investments	$ 176,831

Note 3. Property and Equipment

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

	December 31,	
	2023	2022
Lab equipment	$ 2,313	$ 2,299
Leasehold improvements	1,713	1,713
Computer equipment	832	817
Office furniture and equipment	520	520
Property and equipment	5,378	5,349
Less accumulated depreciation	(5,154)	(5,122)
Property and equipment, net of accumulated depreciation	$ 224	$ 227

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, 2023 was 2.58 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, $ 0.7 million and $ 0.7 million for the twelve months ended December 31, 2023, 2022 and 2021, 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, 2023, 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, 2023 (in thousands):

Assets	
Operating Lease Right-of-Use Assets	$ 1,482
Liabilities	
Operating Lease Short-term Liabilities (recorded within Accrued liabilities)	$ 642
Operating Lease Long-term Liabilities (recorded within Lease-related obligations)	1,177
Total Operating Lease Liabilities	$ 1,819

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

Years Ending December 31,	As of December 31, 2023
2024	759
2025	781
2026	467
Total future minimum rental payments	$ 2,007
Less amount of lease payments representing interest	188
Total present value of lease payments	$ 1,819

For the twelve months ended December 31, 2023 and 2022, the Company made lease payments of approximately $ 0.7 million and $ 0.6 million, respectively, which are included in operating cash flows.

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, 2023 and 2022, the Company had recorded a $ 0.1 million provision for potential refundable amounts.

Note 5. Stockholders' Equity (Deficit)

Common Stock

The Company's common stock consists of 200 million authorized shares at December 31, 2023 and 2022, and 88.9 million and 88.1 million shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively.

Shares Reserved for Future Issuance

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

	December 31,	
	2023	2022
For exercise of outstanding common stock options	18,336,656	15,076,365
For delivery upon vesting of outstanding restricted stock units	895,361	920,533
For future equity awards under the 2013 Equity Incentive Plan	2,257,711	1,466,603
For future purchases under the 2013 Employee Stock Purchase Plan	2,179,399	2,186,097
Total shares of common stock reserved for future issuances	23,669,127	19,649,598

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 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,		
	2023	2022	2021
Expected volatility	83.20 %	74.27 %	95.84 %
Expected term (in years)	5.7	6.0	6.0
Weighted-average risk-free interest rate	3.87 %	1.91 %	0.71 %
Expected dividend yield	— %	— %	— %
Weighted-average fair value per option	$ 1.13	$ 3.33	$ 6.67

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, 2021	11,649,592	$ 6.27	7.65	
Granted	4,217,275	5.12	—	
Exercised	(271,079)	2.24	—	
Forfeited and expired	(519,423)	6.93	—	
Balance, December 31, 2022	15,076,365	$ 6.00	7.32	
Granted	3,861,060	1.59	—	
Exercised	—	—	—	
Forfeited and expired	(600,769)	5.56	—	
Balance, December 31, 2023	18,336,656	$ 5.09	6.57	$ —
Exercisable at December 31, 2023	12,395,052	$ 5.68	5.61	$ —
Vested or expected to vest at December 31, 2023	17,530,966	$ 5.18	6.46	$ —

As of December 31, 2023, there was approximately $ 11.2 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 1.95 years.

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

	Years Ended December 31,		
	2023	2022	2021
Weighted-average grant-date fair value per share of options granted	$ 1.13	$ 3.33	$ 6.67
Total intrinsic value of options exercised	$ —	$ 114	$ 3,496
Total fair value of shares vested	$ 12,834	$ 12,721	$ 8,642

The following table summarizes, at December 31, 2023, 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
0.00 to 1.36	1,293,800	9.84	$ 1.03	1,857	$ 1.11
1.37 to 2.08	4,901,027	7.41	$ 1.94	2,987,651	$ 1.95
2.09 to 3.13	3,198,545	5.39	2.37	3,039,410	2.35
3.14 to 5.60	1,473,488	4.36	4.63	1,399,404	4.63
5.61 to 7.86	3,664,378	7.59	5.81	1,996,046	5.95
7.87 to 53.74	3,805,418	5.24	12.29	2,970,684	13.16
0.00 to 53.74	18,336,656	6.57	$ 5.09	12,395,052	$ 5.68

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 is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

The Company has reserved a total of 4,761,471 shares of common stock to be purchased under the ESPP, of which 2,179,399 and 2,186,097 shares remained available for purchase at December 31, 2023 and 2022, 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 429,233 and 535,255 shares of common stock pursuant to the ESPP for the years ended December 31, 2023 and 2022, 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,		
	2023	2022	2021
Expected volatility	94.64 %	104.88 %	97.54 %
Expected term (in years)	1.50	1.28	0.71
Weighted-average risk-free interest rate	4.63 %	2.63 %	0.25 %
Expected dividend yield	— %	— %	— %
Weighted-average option value per share	$ 0.75	$ 1.97	$ 6.55

As of December 31, 2023, the Company had a liability of $ 0.3 million representing employees' contributions to the ESPP.

Restricted Stock Units

For the years ended December 31, 2023 and 2022, 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, 2023 and 2022, the Company issued 445,940 and 363,527 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, 2022	920,533	$ 4.82
Granted	561,404	1.94
Share issuance	(445,940)	3.83
Forfeited	(140,636)	4.84
Balance, December 31, 2023	895,361	$ 3.49

The total unrecognized compensation cost related to the non-vested RSUs as of December 31, 2023 was $ 2.3 million and will be recognized over a weighted average period of approximately 2.15 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,		
	2023	2022	2021
Income Statement Classification:			
Research and development expense	$ 7,092	$ 8,267	$ 6,611
General and administrative expense	10,365	7,018	5,649
Total stock-based compensation expense	$ 17,457	$ 15,285	$ 12,260

Cash received from exercises under all share-based payment arrangements for 2023, 2022 and 2021 was $ 0.5 million, $ 1.5 million and $ 4.6 million, respectively. There was no actual tax benefit realized for the tax deductions from exercises of the share-based payment arrangements during 2023, 2022 or 2021.

In December 2022, related to the Company's announcement of a reduction in workforce, further discussed in Note 10, certain vested stock options were modified to extend their exercise period from 90 days to 12 months. In addition, certain outstanding stock option and RSU grants received accelerated vesting as if the service period of the terminated employee continued for up to an additional 12-month period. Related to this, the Company recorded expense totaling approximately $ 1.0 million ratably from the announcement date through the date of termination with approximately $ 0.4 million of that total being recognized during the twelve months ended December 31, 2022 and an additional $ 0.6 million being recognized during the twelve months ended December 31, 2023.

In January 2023, the Company extended the post-termination exercise period from 90 days to three years for stock option grants made to non-employee members of our Board of Directors. This extension applies to all future grants as well as all then-outstanding grants. Related to this extension, the Company recorded approximately $ 0.3 million of expense during the twelve months ended December 31, 2023.

In September 2023, the Company's then CEO transitioned to Chairman of the Board of Directors. Per the Company's equity incentive plan, as there was no break in continuous service, the former CEO's equity grants continue to vest on their normal schedule and remain outstanding, contingent upon continued service. In matching the grant expense to the service period for the role in which the grants were originally made, the Company recognized approximately $ 5.1 million in stock-based compensation during the twelve months ended December 31, 2023. This amount is recorded in general and administrative expenses.

At-The-Market Equity Offering; Shelf Registration Statement

On August 10, 2020, we entered into an Open Market Sale Agreement SM (the Prior 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. As of August 9, 2023, the Form S-3 shelf registration statement that registered the shares of common stock available for sale under the Prior Jefferies Sales Agreement expired at the end of its three-year term, and is no longer available for use. We have not sold any shares of our common stock under the Prior Jefferies Sales Agreement. On February 29, 2024, we terminated the Prior Jefferies Sales Agreement with Jefferies LLC in connection with a new sales agreement by and between Jefferies and us, as discussed below.

On May 6, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC, which was subsequently amended in March 2022 to convert to a non-automatic shelf registration statement. This registration statement enables us to offer for sale, from time to time, in one or more offerings, up to $ 250 million in the aggregate, of common stock, debt securities, warrants, rights and/or units, and will remain in effect for up to three years from the date it became effective. We have made no sales of shares of our securities under the shelf registration statement.

On February 29, 2024, we entered into an Open Market Sale Agreement SM (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. On the same day, we will file a shelf registration statement on Form S-3 with the SEC, which contains a base prospectus, covering up to a total aggregate offering price of $ 250 million of our common stock, preferred stock, debt securities and warrants to purchase any of such securities, and a sales agreement prospectus, covering the offering, issuance and sale of up to a maximum aggregate offering price of $ 75 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. The $ 75 million of shares that may be issued and sold from time to time under the Jefferies Sales Agreement is included in the $ 250 million of securities that may be offered, issued and sold by us pursuant to our 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. The net proceeds to the Company from this offering were approximately $ 107.8 million, including the full exercise of the Underwriters' option to purchase additional shares, 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

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. For the year ended December 31, 2022, the Company recorded net income and recorded a small amount of state income tax expense. The Company has net operating losses for the tax year December 31, 2023.

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.

Income tax expense has been recorded for the period ended December 31, 2022. No income tax expense or benefit has been recorded for the years ended December 31, 2023 or 2021. This is due to the establishment of a valuation allowance against the

deferred tax assets generated during those periods. At December 31, 2023, 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.

The provision for income tax expense includes the following as of December 31, 2023, 2022, and 2021:

	December 31,		
	2023	2022	2021
Current:			
Federal	$ —	$ —	$ —
State	—	36	—
Total	—	36	—
Deferred:			
Federal	—	—	—
State	—	—	—
Total	—	—	—
Total Tax Expense	$ —	$ 36	$ —

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, 2023, 2022, and 2021 (in thousands, except percentages):

	2023		2022		2021	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	$ (17,240)	21.0 %	$ 36,163	21.0 %	$ (36,379)	21.0 %
State income taxes	(2,275)	2.8 %	441	0.2 %	(8,060)	4.7 %
Research and development credits	(3,726)	4.5 %	(3,312)	(1.9)%	(1,565)	0.9 %
In process R&D	—	— %	—	— %	26,395	(15.2)%
Permanent items	1,365	(1.7)%	1,135	0.7 %	711	(0.4)%
Provision to return adjustments	31	(0.1)%	1,091	0.6 %	126	(0.1)%
Effect of change in state tax rate	(1,091)	1.3 %	4,405	2.6 %	3,478	(2.0)%
Removal of excess tax benefit	—	— %	—	— %	—	— %
Increase in unrecognized tax benefits	603	(0.6)%	828	0.5 %	439	(0.3)%
Current year forfeitures	51	(0.1)%	54	— %	435	(0.3)%
Change in valuation allowance	22,282	(27.1)%	(40,769)	(23.7)%	14,420	(8.3)%
Net benefit	$ —	— %	$ 36.0	— %	$ —	— %

The components of deferred tax assets and liabilities at December 31, 2023 and 2022 were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Domestic net operating loss carryforwards	$ 90,340	$ 84,147
Research and development expenses	1,812	1,520
Capitalized Section 174 expenses	23,541	12,425
License fees	11,005	11,509
Research and development credits	22,638	20,166
Capital loss carryforwards	448	428
Accrued bonuses	815	722
Share-based compensation	9,012	6,132
Other	959	1,333
Total gross deferred tax assets	160,570	138,382
Valuation allowance	(160,218)	(137,936)
Total deferred tax assets	352	446
Deferred tax liabilities:		
Right-of-use asset	(352)	(446)
Total deferred tax liabilities	(352)	(446)
Total deferred tax assets and liabilities, net	$ —	$ —

At December 31, 2023, the Company had net operating loss carryforwards for federal and state tax purposes of approximately $ 423.2 million and $ 416.0 million, respectively. At December 31, 2022, the Company had net operating loss carryforwards for federal and state tax purposes of approximately $ 394.8 million and $ 394.4 million, respectively. Federal losses of $ 175.4 million begin to expire in 2035 and $ 247.7 million of the federal losses carryforward indefinitely. State losses of $ 413.0 million begin to expire in 2024 and $ 3.0 million of the state losses carryforward indefinitely. There was no tax benefit related to the utilization of net operating losses in 2023. In addition, the Company has tax credit carryforwards for federal tax purposes of approximately $ 29.9 million as of December 31, 2023. Of the $ 29.9 million, $ 0.1 million expired in 2022. The Company also has capital loss carryforwards for federal tax purposes of $ 0.4 million, which begin to expire in 2024. 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 2021, 2022 and 2023, and as such, has no undistributed earnings.

The Company acquired Oncoceutics, Inc. in 2021 and is including the activity for 2022 and 2023 in its consolidated financial statements.

In general, if the Company experiences a greater than 50% change, by value, in its equity ownership over a three-year period, utilization of its 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 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 an ownership change under Section 382 of the Code 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 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, 2023.

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, 2023 and 2022, as follows (in thousands):

Balance at December 31, 2021	$	4,734
Increases related to 2022		828
Increases related to prior periods		—
Balance at December 31, 2022		5,562
Increases related to 2023		736
Decreases related to prior periods		(121)
Balance at December 31, 2023	$	6,177

On November 18, 2021, Governor Roy Cooper signed into law the 2021 Appropriations Act (2021 Appropriations Act) which phases out the corporate income tax for North Carolina. The 2021 Appropriations Act 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 in 2021 and $ 0.6 million in 2022.

The Company has determined that it had no other material uncertain tax benefits for the year ended December 31, 2023. As of December 31, 2022, 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 2003 through 2022. 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, 2023, 2022 and 2021.

The Tax Act subjects a "United States shareholder" for U.S. federal income tax purposes to tax 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 2021, 2022 or 2023; therefore, no GILTI tax has been recorded for the years ended December 31, 2021, 2022 and 2023.

Note 7. Significant Agreements

BARDA 2022 Procurement and Development Contract

On August 26, 2022, the Company entered into a procurement contract, as amended, (the BARDA Agreement) with BARDA for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA® to the U.S. government. The BARDA Agreement consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). Under the terms of the BARDA Agreement, the base period activities are valued at approximately $ 127 million, consisting of an initial shipment of 319,000 treatment courses of TEMBEXA to be procured and shipped to the Strategic National Stockpile for an aggregate purchase price of approximately $ 115 million, and reimbursement for certain post-marketing activities of approximately $ 12 million. The options under the BARDA Agreement, which are exercised at the sole discretion of BARDA, are valued at approximately $ 553 million (if all such options are exercised during the 10-year contract period), which consists of options to purchase up to an additional 1.381 million treatment courses of TEMBEXA for an aggregate purchase price of approximately $ 551 million and funding for certain post-marketing activities of approximately $ 2 million.

In connection with the sale of the TEMBEXA franchise to Emergent, the BARDA Agreement was novated to Emergent in December 2022. In accordance with federal regulations, the terms of the novation agreement require that the company guarantee the performance of all obligations transferred to Emergent should Emergent not have the ability to deliver on the terms of the BARDA Agreement. In this instance BARDA may request that we perform the obligations in place of Emergent.

Emergent Biodefense Operations Lansing LLC

On September 26, 2022, the Company completed the Asset Sale to Emergent of the Company's exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale). Emergent paid the Company an upfront cash payment of approximately $ 238 million upon the closing of the Asset Sale. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from Emergent: (i) up to an aggregate of approximately $ 124 million in milestone payments payable upon the exercise of the options under the BARDA Agreement for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA to the U.S. government; (ii) royalty payments equal to 15 % of the gross profits from the sales of TEMBEXA made outside of the United States; (iii) royalty payments equal to 20 % of the gross profits from the sales of TEMBEXA made in the United States in excess of 1.7 million treatment courses; and (iv) up to an additional $ 12.5 million upon the achievement of certain other developmental milestones. The effects of recording certain adjustments associated with contingent consideration related to TEMBEXA have been excluded as the Company has made a policy election to account for these amounts when the contingency has been resolved in accordance with Accounting Standards Codification 450, *Contingencies*.

The Company continues to provide operational support to Emergent in furtherance of its obligations under both the Asset Purchase Agreement (and related agreements) and the BARDA Agreement. The BARDA Agreement was novated to Emergent in December 2022. Under the Asset Purchase Agreement, the Company recognized approximately $ 0.2 million and $ 0.5 million of contract revenue for support provided for the twelve months ended December 31, 2023 and 2022, respectively.

The sale of TEMBEXA constitutes a significant disposition of a business, however, the Company determined the disposition does not represent a strategic shift, and accordingly, the Company has not accounted for the disposition as a discontinued operation. The Company recorded a $ 229.7 million net gain on sale of business in other income (loss) on the Consolidated Statement of Operations and Comprehensive Income (Loss) for the twelve months ended December 31, 2022. The net gain consists of the following assets and liabilities transferred in accordance with the Asset Purchase Agreement (in thousands):

	As of September 26, 2022
Up-front cash payment	$ 237,987
Liabilities assumed by Emergent	1,423
Inventory transferred to Emergent	(5,227)
Prepaids transferred to Emergent	(511)
Transaction costs incurred	(4,002)
Net gain	**$ 229,670**

TEMBEXA Procurement Agreements

In June 2022, the Company entered into a Supply Agreement (the Supply Agreement) with a third-party outside of North America (the Purchaser), pursuant to which the Company was responsible for supplying to the Purchaser, and the Purchaser was responsible for purchasing from the Company, TEMBEXA treatment courses for use in a jurisdiction outside of the United States. Under the terms of the Supply Agreement, the Purchaser paid the Company an aggregate purchase price of approximately $ 9.3 million, in two equal installments in June 2022 and July 2022. The Company recognized $ 9.3 million of procurement revenue under the Supply Agreement for the twelve months ended December 31, 2022.

Additionally, in June 2022, the Public Health Agency of Canada (PHAC) awarded a Contract (PHAC Contract) to the Company, pursuant to which PHAC agreed to purchase up to approximately $ 25.3 million (CAD $ 33.0 million) of TEMBEXA treatment courses for use in Canada. Substantially all of the procurement was delivered and accepted by PHAC in July 2022, completing the performance obligation for those shipments and resulting in $ 22.6 million of procurement revenue for the twelve months ended December 31, 2022. PHAC assigned the PHAC Contract to Emergent in November 2022. The remaining deliveries of treatment courses were delivered by Emergent and are subject to the royalty terms of the Asset Purchase Agreement applicable to gross profits outside the United States. The Company recognized approximately $ 0.4 million of royalty revenue in the twelve months ended December 31, 2022.

BARDA 2011 Research and Development Contract

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 year ended December 31, 2021, the Company recognized contract revenue under this contract of $ 1.6 million.

Ohara Agreement

In 2019, Oncoceutics, Inc., a Delaware corporation (Oncoceutics) which was subsequently acquired by the Company in January 2021, 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 double-digit 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 double-digit tiered royalties based on the aggregate annual net sales of all licensed products, as defined in the agreement, in the CR Sanjiu Territory.

Note 8. DSTAT Contract Close-out

In May 2022, the Company made the decision to discontinue the development of DSTAT for the treatment of AML. Effective July 12, 2022, the Company terminated the License and Development Agreement with Cantex. As a result, the Company recorded an accrual of expenses to close-out the DSTAT vendor contracts.

The following table summarizes the incremental contract close-out costs (in thousands) recorded for the twelve months ended December 31, 2022:

	Contract Close-out Costs
Research & development	$ 791
General & administrative	8
Total contract close-out expenses	$ 799

The following table sets forth the accounts payable and accrual activity for contract close-out costs (in thousands) for the twelve months ended December 31, 2022.

	Contract Close-out Costs
Balance at June 30, 2022	$ 4,539
Revised estimates	$ (746)
Payments	$ (2,482)
Balance at December 31, 2022	$ 1,311

The following table sets forth the accounts payable and accrual activity for contract close-out costs (in thousands) for the twelve months ended December 31, 2023.

		Contract Close-out Costs
Balance at December 31, 2022	$	1,311
Revised estimates	$	(189)
Payments	$	(1,122)
Balance at December 31, 2023	$	—

For the twelve months ended December 31, 2023, the revised accrual estimates resulted in a decrease to research and development expenses of $ 189,000 .

Note 9. Oncoceutics Acquisition

On January 7, 2021, we entered into an agreement to acquire Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, a novel potential class of compounds. As consideration for the acquisition, the Company (a) paid an upfront cash payment of approximately $ 25.0 million, (b) issued an aggregate of 8,723,769 shares of the Company's common stock, (c) made an additional cash payment of $ 14.0 million 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. Pursuant to the merger agreement we have certain diligence obligations with respect to further development and commercialization of the Oncoceutics product candidates.

The promissory note totaling $ 14.0 million 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 diffuse 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 10. Restructuring Costs

In December 2022, the Company made the decision to restructure its operations, which included a reduction in workforce of 20 full-time employees. During the twelve months ended December 31, 2022, the Company recorded expense for one-time employee termination benefits of $ 1.9 million, which included a ratable share of the total stock compensation expense that resulted from the modifications of stock option agreements of employees. The total amount of stock compensation expense related to the reduction in workforce equals $ 1.0 million of which $ 0.4 million was recorded during the twelve months ended December, 31, 2022 and $ 0.6 million was recognized during the twelve months ended December 31, 2023.

The following table summarizes the restructuring charges (in thousands) recorded for the twelve months ended December 31, 2022:

	Employee Termination Benefits
Research and development	$ 1,768
General and administrative	86
Total restructuring expenses	$ 1,854

The following table sets forth the accrual activity for employee termination benefits (in thousands) for the twelve months ended December 31, 2023:

	Employee Termination Benefits
Balance at December 31, 2022	$ 1,442
Revised estimates	(162)
Payments	(1,248)
Balance at December 31, 2023	$ 32

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, 2023, and events which occurred subsequently but were not recognized in the financial statements.

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, 2023, 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, 2023.

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

Trading Arrangements

None .

ITEM 9B. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

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 sections headed “Election of Directors,” “Executive Officers,” and “Information Regarding the Board of Directors and Corporate Governance” in our Proxy Statement for our 2024 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, 2023, 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 and Director 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 sections headed “Transactions With Related Persons” and “Information Regarding the Board of Directors and Corporate Governance” 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 AND 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** (1)	Agreement and Plan of Merger, dated January 7, 2021, by and among the Registrant, Oncoceutics, Merger Sub.
3.1 (2)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2 (3)	Amended and Restated Bylaws of the Registrant.
4.1 (4)	Form of Common Stock Certificate of the Registrant.
4.2(18)	Description of Common Stock.
10.1+ (5)	Form of Indemnity Agreement by and between the Registrant and its Directors and Officers.
10.2+ (5)	Chimerix, Inc. 2013 Employee Stock Purchase Plan.
10.3+(6)	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.
10.4+ (7)	Chimerix, Inc. 2013 Equity Incentive Plan, as amended.
10.5+ (8)	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise for Inducement Grant Outside of 2013 Equity Incentive Plan
10.6+ (9)	Letter Agreement with Michael Sherman, dated June 27, 2023.
10.7+ (9)	Amended Employment Offer Letter to Michael Andriole, dated June 27, 2023.
10.8+ (9)	Chimerix, Inc. Non-Employee Director Compensation Policy , as amended, dated June 27, 2023.
10.9+ (10)	Chimerix, Inc. Officer Severance Benefit Plan, as amended.
10.10 (5)	Office Lease by and between the Registrant and ACP 2505 Meridian LLC dated September 1, 2007, as amended.
10.11 (11)	Fifth Amendment to Office Lease dated July 2, 2014 by and between the Registrant and AREP Meridian I LLC.
10.12 (12)	Sixth Amendment to Office Lease dated April 28, 2015 by and between the Registrant and IVC Meridian TT O, LLC.
10.13 (13)	Seventh Amendment to Office Lease dated March 10, 2017 by and between the Registrant and IVC Meridian TT O, LLC.
10.14 (14)	Lease Agreement by and between the Registrant and Northwood RTC LLC dated March 10, 2014.
10.15 (15)	Eighth Amendment to Office Lease dated July 13, 2017 by and between the Registrant and IVC Meridian TT O, LLC.
10.16 (16)	Ninth Amendment to Office Lease, dated June 24, 2020, by and between the Registrant and BRI 1875 Meridian, LLC.
10.17** (16)	Second Amendment to Lease Agreement, dated July 30, 2020, by and between the Registrant and CLPF-Research Center, LLC.
10.18 (17)	First Amendment to Industrial Building Lease dated December 14, 2017 by and between Registrant and CLPF - Research Center, LLC.

10.19+[18]	Employment Offer Letter to Allen Melemed dated May 7, 2020.
10.20+[19]	Employment Offer Letter to Michael A. Alrutz dated May 19, 2012.
10.21** #[20]	Loan and Security Agreement, dated January 31, 2022, by and between the Registrant and Silicon Valley Bank.
10.22	First Amendment to Loan and Security Agreement, dated November 21, 2 023, by and between the Registra nt and Silicon Valley Bank.
10.23**#[21]	Asset Purchase Agreement, dated May 15, 2022, by and between the Company and Emergent BioSolutions Inc.
10.24**#[22]	First Amendment to Asset Purchase Agreement, dated September 26, 2022, by and between the Registrant, Emergent BioSolutions Inc. and Emergent Biodefense Operations Lansing LLC.
10.25+[23]	Employment Offer Letter to Thomas J. Riga, dated October 2, 2023.
10.26+[24]	Employment Offer Letter to Michelle LaSpaluto , dated November 30, 2023.
10.27	Open Market Sale Agreement[SM] dated February 29, 2024, by and between the Company and Jefferies LLC.
10.28	Directorship Offer Letter to Lisa L. Decker, PhD, dated December 28, 2023.
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.
97.1	Chimerix, Inc. Incentive Compensation Recoupment Policy, adopted on November 14, 2023.
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 Annual Report on Form 10-K (No. 001-35867) filed with the SEC on February 25, 2021.
(2)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on April 16, 2013.
(3)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on December 9, 2022.
(4)	Incorporated by reference to Chimerix, Inc.'s Registration Statement on Form S-1 (No. 333-187145), as amended , filed with the SEC on March 27, 2013 .
(5)	Incorporated by reference to Chimerix, Inc.'s Registration Statement on Form S-1 (No. 333-187145), as amended, filed with the SEC on March 8, 2013.
(6)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 7, 2016.
(7)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on June 23, 2014.
(8)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 8, 2019.
(9)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on June 27, 2023.
(10)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on April 18, 2022.
(11)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on November 7, 2014.
(12)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 11, 2015.
(13)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on May 9, 2017.
(14)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on March 14, 2014.
(15)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 7, 2017.
(16)	Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 10, 2020.
(17)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 1, 2018.
(18)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 2, 2023.
(19)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 5, 2019.
(20)	Incorporated by reference to Chimerix, Inc.'s Annual Report on Form 10-K (No. 001-35867) filed with the SEC on March 1, 2022.
(21)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on May 18, 2022.
(22)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on September 28, 2022.
(23)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on November 16, 2023.
(24)	Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on December 4, 2023.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

Chimerix, Inc.

Date: February 29, 2024 By: /s/ Michael T. Andriole

Michael T. Andriole

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 T. Andriole and Michelle LaSpaluto, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her 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 T. Andriole Michael T. Andriole	President, Chief Executive Officer and Director (Principal Executive Officer)	February 29, 2024
/s/ Michelle LaSpaluto Michelle LaSpaluto	Chief Financial Officer (Principal Financial Officer)	February 29, 2024
/s/ David Jakeman David Jakeman	Vice President of Finance and Accounting (Principal Accounting Officer)	February 29, 2024
/s/ Michael A. Sherman Michael A. Sherman	Chair of the Board of Directors	February 29, 2024
/s/ Martha J. Demski Martha J. Demski	Lead Independent Director	February 29, 2024
/s/ Lisa L. Decker, PhD Lisa L. Decker, PhD	Member of the Board of Directors	February 29, 2024
/s/ Patrick Machado Patrick Machado	Member of the Board of Directors	February 29, 2024
/s/ Robert J. Meyer Robert J. Meyer, MD	Member of the Board of Directors	February 29, 2024
/s/ Fred A. Middleton Fred A. Middleton	Member of the Board of Directors	February 29, 2024
/s/ Pratik S. Multani Pratik S. Multani, MD	Member of the Board of Directors	February 29, 2024
/s/ Victoria Vakiener Victoria Vakiener	Member of the Board of Directors	February 29, 2024

Exhibit 10.22

[*] = 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.

FIRST AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT** to Loan and Security Agreement (this " **Agreement**") is entered into as of November 21, 2023, by and between Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("**Bank**") and Chimerix, Inc. **,** a Delaware corporation ("**Borrower**").

Recitals

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of January 31, 2022 (as the same may from time to time be amended, modified, supplemented or restated, the "Loan Agreement"). Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Bank amend the Loan Agreement to make certain revisions to the Loan Agreement as more fully set forth herein.

D. Bank has agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

Agreement

Now, Therefore, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Agreement shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

1.1 Section 1.1 (Revolving Line). Subsection 1.1(a) of Section 1.1 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"(a) Availability. Subject to the terms and conditions of this Agreement (including the terms and conditions of Section 1.7 hereof), Bank shall make Advances not exceeding the Revolving Line. Amounts borrowed under the Revolving Line may be prepaid or repaid as set forth on Schedule I hereto."

1.2 Section 1.7 (Overadvances). Section 1.7 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"**1.7 Overadvances**. If, at any time, (i) the sum of the aggregate outstanding principal amount of the Advances, exceeds the Revolving Line or (ii) Borrower fails to maintain unrestricted cash at Bank in an amount that is at all times equal to or greater than the greater of (a) one and one-half times (1.5x) the outstanding principal balance under the Revolving Line or (b) the outstanding principal balance under the Revolving Line plus trailing six (6) month Cash Burn for the most recently ended month, each as determined by Bank in its reasonable business discretion, 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 three percent [*]."

1.3 Section 1.9 (Fees). Subsection 1.9(d) of Section 1.9 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"(d) Unused Revolving Line Facility Fee. Payable quarterly in arrears on the last calendar day of the calendar quarter occurring 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 thirty-five hundredths of one percent (0.35%) 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. Notwithstanding the foregoing, Borrower shall not be required to pay the Unused Revolving Line Facility for the fiscal quarters ended March 31, 2023, June 30, 2023, and September 30, 2023."

1.4 Section 2.1 (Conditions Precedent to Initial Credit Extension). Subsection 2.1(h) of Section 2.1 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"(h) Reserved; and"

1.5 Section 2.2 (Conditions Precedent to all Credit Extensions). Section 2.2 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"**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;

(c) a Material Adverse Change shall not have occurred and be continuing; and

(d) within ten (10) Business Days prior to the date of any Credit Extension, to the extent not delivered in accordance with Sections 5.3(c) and 5.3(d) hereof, receipt of Borrower's 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 the month ending at least thirty (30) days prior to such date, in a form reasonably acceptable to Bank, together with a duly completed Compliance Statement."

1.6 Section 4.3 (Accounts Receivable; Inventory). Section 4.3 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"**4.3 Reserved.**"

1.7 Section 5.3 (Financial Statements, Reports). Subsections 5.3(a) and 5.3(b) of Section 5.3 of the Loan Agreement hereby are amended and restated in their entirety, to read as follows:

"(a) Reserved;

(b) Reserved;"

1.8 Section 5.4 (Accounts Receivable). Section 5.4 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"**5.4 Reserved.**"

1.9 Section 5.7 (Access to Collateral; Books and Records). Section 5.7 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"**5.7 Reserved**."

1.10 Section 5.9 (Accounts). Subsection 5.9(a) of Section 5.9 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"(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 thirty percent (30%) of the Dollar Equivalent value of all deposit account balances of Borrower, its Subsidiaries and any Guarantors, on a consolidated basis, at all financial institutions."

1.11 Section 5.10 (Financial Covenants). Section 5.10 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"**5.10 Reserved**."

1.12 Section 12.1 (Accounting and Other Terms). Subsection (a) of Section 12.1 of the Loan Agreement hereby is amended and restated in its entirety, to read as follows:

"(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. "

1.13 Section 12.2 (**Definitions**). The following terms and their respective definitions set forth in Section 12.2 of the Loan Agreement hereby are amended and restated in their entirety and replaced with the following:

"**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.

1.14 Section 12.2 (**Definitions**). The following terms and their respective definitions set forth in Section 12.2 of the Loan Agreement hereby are deleted in their entirety:

"**ABPO**"; "**Availability Amount**"; "**BARDA Procurement Contract**"; "**Borrowing Base**"; "**Borrowing Base Statement**"; "**Cash Collateral Account**"; "**CLIN**", "**Eligible Accounts**"; "**Eligible Purchase Orders**"; "**Liquidity**"; "**Reserves**"; "**Streamline Balance**"; "**Streamline Period**".

1.15 Exhibit A (Compliance Statement). Exhibit A of the Loan Agreement hereby is replaced in its entirety by Exhibit A attached hereto.

1.16 Schedule I (LSA Provisions). Schedule I of the Loan Agreement hereby is replaced in its entirety with Schedule I attached hereto.

3. Limitation of Agreement.

1.1 This Agreement is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

1.2 This Agreement shall be construed in connection with and as part of the Loan Documents, and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. Borrower represents and warrants to Bank as follows:

1.1 No Event of Default has occurred and is continuing;

1.2 Borrower has the power and authority to execute and deliver this Agreement and to perform its obligations under the Loan Agreement;

1.3 The organizational documents of Borrower delivered to Bank in connection with this Agreement remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

1.4 The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement have been duly authorized by all necessary action on the part of Borrower;

1.5 The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

1.6 The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on either Borrower, except as already has been obtained or made; and

1.7 This Agreement has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Prior Agreement. Except as set forth in Section 6 below, the Loan Documents are hereby ratified and reaffirmed and shall remain in full force and effect. This Agreement is not a novation and the terms and conditions of this Agreement shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. In the event of any conflict or inconsistency between this Agreement and the terms of such documents, the terms of this Agreement shall be controlling, but such document shall not otherwise be affected or the rights therein impaired.

6. Updated Perfection Certificate. In connection with this Agreement, Borrower has delivered an updated Perfection Certificate (the " **Updated Perfection Certificate** "). Borrower and Bank acknowledge and agree that, from and after the date of this Agreement, each reference in the Loan Documents to the "Perfection Certificate" shall be deemed to be a reference to the Updated Perfection Certificate. Borrower acknowledges, confirms and agrees the disclosures and information Borrower provided to Bank in the Updated Perfection Certificate have not changed as of the date hereof.

7. Integration. This Agreement and 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 this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

8. Counterparts. This Agreement may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

9. Effectiveness. This Agreement shall be deemed effective upon (a) the due execution and delivery to Bank of (i) this Agreement by each party hereto, (ii) the Updated Perfection Certificate, and (iii) a duly executed Control Agreement with JPMorgan Chase Bank, N.A., and (b) Borrower's payment of all Bank Expenses due and owing as of the date hereof, which may be debited from any of Borrower's accounts at Bank.

10. Miscellaneous.

1.1 This Agreement shall constitute a Loan Document under the Loan Agreement; the failure to comply with the covenants contained herein shall constitute an Event of Default under the Loan Agreement; and all obligations included in this Agreement (including, without limitation, all obligations for the payment of principal, interest, fees, and other amounts and expenses) shall constitute obligations under the Loan Agreement and secured by the Collateral.

1.2 Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

11. Governing Law. This Agreement and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

[*Balance of Page Intentionally Left Blank*]

In Witness Whereof, the parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

BANK:	**BORROWER:**
First-Citizens Bank & Trust Company	Chimerix, Inc.
By: /s/ Scott McCarty	By: /s/ Mike Andriole
Name: Scott McCarty	Name: Mike Andriole
Title: Director	Title: President & CEO

ACTIVE\302573994.6

EXHIBIT A

COMPLIANCE STATEMENT

Date: _____

TO: SILICON VALLEY BANK, a division of First-Citizens Bank & Trust Company
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
Board approved projections	FYE within 30 days and as amended/updated	Yes No
UBS Account Statements	Upon demand by Bank	Yes No

Accounts:

1. Borrower's total balance, including cash, in accounts in the name of Borrower, its Subsidiaries and any Guarantors maintained with Bank or Bank's Affiliates: $_____

2. Total aggregate balance, including cash, of Borrower at all institutions wherever located: $_____

3. Is Borrower's , its Subsidiaries and any Guarantor's aggregate balance, including cash, in accounts in the name of Borrower, its Subsidiaries or any Guarantors maintained with Bank or Bank's Affiliates greater than or equal to 30% of the total aggregate balance, including cash, of Borrower, its Subsidiaries and any Guarantors at all institutions wherever located?

   Yes, in compliance _____ No, not in compliance _____

4. Institutions (other than Bank) where Borrower maintains accounts and balances in such accounts:

Institution Name	Account Number	Balance	Control Agreement in favor of Bank obtained?

Yes, in compliance _____ No, not in compliance _____

The following are the exceptions with respect to the statements above: (If no exceptions exist, state “No exceptions to note.”)

ACTIVE\302573994.6

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 September 30, 2026.

Exhibit 10.27

OPEN MARKET SALE AGREEMENT[1]

February 29, 2024

JEFFERIES LLC
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

Chimerix, Inc., a Delaware corporation (the "**Company**"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "**Agent**"), shares of the Company's common stock, par value $0.001 per share (the "**Common Shares**"), having an aggregate offering price of up to $75,000,000 on the terms set forth in this agreement (this "**Agreement**").

Section 1. DEFINITIONS

(a) Certain Definitions. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

"**Affiliate**" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first- mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agency Period**" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.

"**Commission**" means the U.S. Securities and Exchange Commission.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

"**Floor Price**" means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less than $1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.

"**Issuance Amount**" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

[1] SM "Open Market Sale Agreement" is a service mark of Jefferies LLC

"**Issuance Notice**" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as Exhibit A that is executed by its Chief Executive Officer, President, Chief Financial Officer or General Counsel.

"**Issuance Notice Date**" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

"**Issuance Price**" means the Sales Price less the Selling Commission.

"**Maximum Program Amount**" means Common Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (as defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (defined below).

"**Person**" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

"**Principal Market**" means The Nasdaq Global Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

"**Sales Price**" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

"**Selling Commission**" means three percent (3%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

"**Settlement Date**" means the second business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

"**Shares**" shall mean the Company's Common Shares issued or issuable pursuant to this Agreement.

"**Trading Day**" means any day on which the Principal Market is open for trading.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date (as defined below) and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a "**Representation Date**"), except as may be disclosed in the Registration Statement or Prospectus (each, as defined below) (including any documents

incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and will file with the Commission a shelf registration statement on Form S-3 that contains a base prospectus (the "**Base Prospectus**"). Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the "**Registration Statement**," and the prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "**Prospectus**," except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "**Prospectus**" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the "**Original Registration Statement**." As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date.

At the time the Registration Statement was or will be originally declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) Compliance with Registration Requirements. Except as of the date of this Agreement, the Original Registration Statement and any Rule 462(b) Registration Statement will have been filed and will be declared effective by the Commission under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the

Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus, when filed, complied or will comply in all material respects with the Securities Act and, if filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system ("**EDGAR**") (except as may be permitted by Regulation S-T under the Securities Act), was substantially identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and as of each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus (as defined below) considered together (collectively, the "**Time of Sale Information**"), did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and as of each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in Section 6 below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

(c) Offering Materials furnished to Agent. As of each Representation Date other than the date of this Agreement, the Company has delivered to the Agent one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as the Agent has reasonably requested.

(d) Not an Ineligible Issuer. The Company currently is not an "ineligible issuer," as defined in Rule 405 of the rules and regulation of the Commission. The Company agrees to notify the Agent promptly upon the Company becoming an "ineligible issuer."

(e) Distribution of Offering Material By the Company. The Company has not distributed and will not distribute, prior to the completion of the Agent's distribution of the Shares, any offering material in connection with the offering and sale of the Shares other than the Prospectus or the Registration Statement.

(f) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization,

moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(g) Authorization of the Shares. The Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly authorized, validly issued, fully paid and nonassessable, and the issuance and sale of the Shares will not be subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(h) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(i) No Material Adverse Change. There has not occurred any material adverse change, or any development involving a prospective material adverse change, in the condition, financial or otherwise, or in the earnings, business, operations or prospects of the Company and its subsidiaries, taken as a whole (any such change is called a "**Material Adverse Change**"), from that set forth in the Registration Statement and the Prospectus.

(j) Independent Accountants. Ernst & Young LLP, who has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) and supporting schedules filed with the Commission or incorporated by reference as a part of the Registration Statement and included in the Prospectus, is an independent registered public accounting firm with respect to the Company within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.

(k) Preparation of the Financial Statements. The financial statements (including the related notes thereto) of the Company incorporated by reference in the Registration Statement and the Prospectus comply as to form in all material respects with the applicable requirements of the Securities Act and present fairly in all material respects the financial position of the Company as of the dates indicated and the results of its operations and the changes in its cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("**GAAP**") applied on a consistent basis throughout the periods covered thereby, except as otherwise noted therein and except in the case of unaudited, interim financial statements, which do not contain certain footnotes as permitted by the rules of the Commission, and any supporting schedules included in or incorporated by reference in the Registration Statement present fairly in all material respects the information required to be stated therein; and the other financial information included in or incorporated by reference in the Registration Statement and the Prospectus has been derived from the accounting records of the Company and, in the case of the financial information under the heading "Dilution," presents fairly in all material respects the information shown thereby. No other financial statements or supporting schedules are required to be included in the Registration Statement or the Prospectus. All disclosures contained in the Registration Statement and the Prospectus that constitute non-GAAP financial measures (as defined by the rules and regulations under the Securities Act and the Exchange Act) comply in all material respects with Regulation G under the Exchange Act and Item 10 of Regulation S-K under the Securities Act, as applicable.

(l) eXtensible Business Reporting Language. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration

Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(m) Incorporation and Good Standing of the Company. The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not be reasonably expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(n) Subsidiaries. The Company does not have any "subsidiaries" (as defined in Regulation S-X of the Exchange Act) other than Oncoceutics, Inc. ("**Oncoceutics**") and Chimerix IRL Limited, and does not have any "significant subsidiaries" (as defined in Regulation S-X) other than Oncoceutics. Each subsidiary of the Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own its property and to conduct its business and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company and its subsidiaries, taken as a whole; all of the issued shares of capital stock of each subsidiary of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and are owned directly by the Company, free and clear of all liens, encumbrances, equities or claims.

(o) Capital Stock Matters. The authorized capital stock of the Company will conform as to legal matters to the description thereof contained in each of the Registration Statement and the Prospectus. The Common Shares outstanding have been duly authorized and are validly issued, fully paid and non-assessable and are not subject to any pre-emptive or similar rights; except as described in or expressly contemplated by the Registration Statement and the Prospectus, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire from the Company, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company, or any contract, commitment, agreement, understanding or arrangement of any kind to which the Company is a party relating to the issuance of any capital stock of the Company, any such convertible or exchangeable securities or any such rights, warrants or options. Except as described in the Registration Statement and the Prospectus, the issuance and sale of the Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of capital stock of the Company, in each case from the Company.

(p) Stock Options. With respect to the stock options (the "**Stock Options**") granted pursuant to the stock-based compensation plans of the Company (the "**Company Stock Plans**"), (i) each Stock Option intended to qualify as an "incentive stock option" under Section 422 of the United States Internal Revenue Code of 1986, as amended (the "**Code**"), so qualifies to the maximum extent permitted by law, (ii) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents and each such grant was timely and appropriately communicated to the grant recipient, (iii) each such grant was made in

accordance with the terms of the Company Stock Plans and all other applicable laws and regulatory rules or requirements, and (iv) each such grant was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company.

(q) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. The Company and its subsidiaries are not (i) in violation of their respective certificates of incorporation or by-laws or similar organizational documents, (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, in each case that is material to the Company and its subsidiaries, taken as a whole, or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except in the case of clauses (ii) and (iii) for any such default, event or violation that would not be reasonably expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole. The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene any provision of applicable law or the certificate of incorporation or by-laws of the Company, or any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party or by which the Company or its subsidiaries is bound or to which any of the property or assets of the Company or its subsidiaries is subject, in each case that is material to the Company, or any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company or its subsidiaries, and no consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the performance by the Company of its obligations under this Agreement, except such as may be required by the securities or Blue Sky laws of the various states or the Financial Industry Regulatory Authority, Inc. ("**FINRA**") in connection with the offer and sale of the Shares.

(r) No Material Actions or Proceedings. There are no legal or governmental proceedings pending or to the knowledge of the Company, threatened to which the Company or any of its subsidiaries is a party or to which any of the properties of the Company or any of its subsidiaries is subject i) other than proceedings accurately described in all material respects in the Registration Statement and the Prospectus and proceedings that would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, or on the power or ability of the Company to perform its obligations under this Agreement or to consummate the transactions contemplated by the Registration Statement and the Prospectus or ii) that are required to be described in the Registration Statement or the Prospectus and are not so described; and there are no statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement that are not described or filed as required. No material labor dispute with the employees of the Company or its subsidiaries exists, except as described in the Registration Statement and the Prospectus, or, to the knowledge of the Company, is imminent; and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that would reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(s) Marketable Title. The Company and its subsidiaries have good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by it which is material to the business of the Company or its subsidiaries, in each case free and clear of all liens, encumbrances and defects except such as are described in the

Registration Statement and the Prospectus or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or its subsidiaries; and any real property and buildings held under lease by the Company and its subsidiaries are held by the Company or such subsidiaries under valid, subsisting and, to the Company's knowledge, enforceable leases with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such property and buildings by the Company or its subsidiaries, in each case except as described in the Registration Statement and the Prospectus.

(t) Each of the Company and its subsidiaries (i) has operated and currently operates its business in compliance with all applicable Health Care Laws (as defined below) and any other applicable requirements of the Food and Drug Administration ("**FDA**"), the Department of Health and Human Services ("**HHS**") and any comparable state, local or foreign regulatory authority to which its business and operations are subject (collectively, "**Regulatory Authorities**"), except where the failures to so comply, whether individually or in the aggregate, would not reasonably be expected to have a Material Adverse Change; (ii) has not received any FDA Form-483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or Regulatory Authority alleging or asserting material non-compliance with (A) any applicable Health Care Laws or (B) any licenses, certificates, approvals, clearances, exemptions, registrations, authorizations, permits and supplements or amendments thereto required pursuant any such applicable Health Care Laws ("**Regulatory Authorizations**"); (iii) possesses such valid and current Regulatory Authorizations required to conduct its business as currently conducted, and is not in violation, in any respect, of any term of any such Regulatory Authorizations, except where failures to possess or comply with the terms of such Regulatory Authorizations would not, whether individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (iv) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or Regulatory Authority or any other third party alleging that any product, operation or activity is in material violation of any Health Care Laws or Regulatory Authorizations and has no knowledge that any Regulatory Authority, governmental authority, or any other third party has threatened any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) has not received written notice that any Regulatory Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Regulatory Authorizations and has no knowledge that any Regulatory Authority is threatening such action, except for such limitations, suspensions, modifications or revocations as would not, whether individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (vi) has no knowledge of any event that has occurred which allows, or after notice or lapse of time would reasonably be expected to allow, revocation or termination or impairment of any Regulatory Authorization, except for such revocations, terminations or impairments as would not, whether individually or in the aggregate, reasonably be expected to have a Material Adverse Change (vi) has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any applicable Health Care Laws or Regulatory Authorizations and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were materially corrected or supplemented by a subsequent submission) except where the failures to file, obtain, maintain, submit or correct the same would not, whether individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (vii) is not a party to or have any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred or non-prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any applicable

Regulatory Authority; and (viii) along with its employees, officers and directors, and, to the Company's knowledge, agents, has not been excluded, suspended or debarred from participation in any government health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion. The term "Health Care Laws" means all Health Care Laws related to the research, investigation, development, production, testing, packaging, labeling, distribution, storage, shipping, transport, marketing, advertising, promotion, sale, export, import, use, handling, control, safety, efficacy, reliability or manufacturing of pharmaceutical products, including, without limitation, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid statute), and any other law pertaining to or governing a government healthcare program; the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal false statements law, 42 U.S.C. 1320a-7b(a); any criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1035, 1347 and 1349 and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq., ("HIPAA"); the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a and 1320a-7b; the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h; the Exclusion Laws, 42 U.S.C. § 1320a-7; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 17921 et seq.; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the Public Health Service Act, 42 U.S.C. § 201 et seq.; the regulations promulgated pursuant to such laws; and any comparable foreign, federal, state and local laws and regulations.

(u) All pre-clinical and clinical studies, tests and trials conducted by or on behalf of or sponsored by the Company or its subsidiaries, or in which the Company or its subsidiaries have participated with respect to their products and product candidates, including without limitation any such studies, tests and trials that are described in the Registration Statement or the Prospectus, or the results of which are referred to in the Registration Statement or the Prospectus, as applicable, were, and if still pending are, being conducted in all material respects in accordance with all applicable Health Care Laws, Regulatory Authorizations and any applicable rules, regulations, protocols and policies to which such studies, tests or trials are subject. The descriptions of the results from such studies, tests and trials contained in the Registration Statement and the Prospectus are accurate in all material respects, and the Company has no knowledge of any other studies, tests or trials not described in the Registration Statement or the Prospectus, the results of which are inconsistent with or call into question the results described or referred to in the Registration Statement or the Prospectus, as applicable. Neither the Company nor its subsidiaries has received any written notices, correspondence or other communications from any Regulatory Authority, institutional review board or other entity having authority over the conduct of such studies, tests, or trials requiring or threatening the termination, material modification, clinical hold or suspension of any such studies, tests or trials being conducted or proposed to be conducted by or on behalf of the Company or its subsidiaries, other than ordinary course communications with respect to modifications in connection with the design and implementation of such studies, tests or trials, and, to the Company's knowledge, there are no reasonable grounds for the same.

(v) The manufacture of the Company's and its subsidiaries' products and product candidates, whether by or on behalf of the Company or its subsidiaries is being conducted in compliance in all material respects with all applicable Health Care Laws. There have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, quality or regulatory compliance of the Company's or its subsidiaries' products (collectively, "**Safety Notices**"). To the Company's knowledge, there are

no facts that would be reasonably likely to result in (a) a material Safety Notice with respect to the Company's or its subsidiaries' products, (b) a material change in labeling of any the Company's or its subsidiaries' products, or (c) a termination or suspension of marketing or testing of any of the Company's or its subsidiaries' products.

(w) Tax Law Compliance. The Company and its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed or have requested extensions thereof (except where the failure to file would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole) and have paid all taxes required to be paid thereon (except for cases in which the failure to pay would not reasonably be expected to have a material adverse effect, or, except as currently being contested in good faith and for which reserves required by GAAP have been created in the financial statements of the Company), and no tax deficiency has been determined adversely to the Company or its subsidiaries which has had (nor does the Company have any notice or knowledge of any tax deficiency which would reasonably be expected to be determined adversely to the Company or its subsidiaries and which would reasonably be expected to have) a material adverse effect.

(x) Company Not an "Investment Company". The Company is not, and after giving effect to receipt of payment for the Shares and the application of the proceeds thereof as described in the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(y) Insurance. The Company and its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are reasonably prudent and customary in the businesses in which it is engaged; since January 1, 2012, the Company and its subsidiaries have not been refused any insurance coverage sought or applied for; and the Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company and its subsidiaries, taken as a whole, except as described in the Registration Statement and the Prospectus.

(z) No Price Stabilization or Manipulation. The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in any stabilization or manipulation of the price of the Shares.

(aa) Related Party Transactions. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders or suppliers of the Company, on the other, that is required by the Securities Act to be described in the Registration Statement and the Prospectus and that is not so described in such documents.

(bb) Exchange Act Compliance. Each document, if any, filed or to be filed pursuant to the Exchange Act and incorporated by reference in the Prospectus complied or will comply when so filed in all material respects with the Exchange Act and the applicable rules and regulations of the Commission thereunder and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(cc) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, employee, agent,

Affiliate or other person acting on behalf of the Company or any subsidiary has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government officials or employees, political parties or campaigns, political party officials, or candidates for political office from corporate funds; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**"), or any applicable anti-corruption laws, rules, or regulations of any other jurisdiction in which the Company or any subsidiary conducts business; or (iv) made any other unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any person. The Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and the Company has instituted and maintains policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(dd) Compliance with Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the U.S. Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority, body or any arbitrator involving the Company or any of its subsidiaries with respect to Anti-Money Laundering Laws is pending, or to the knowledge of the Company, threatened.

(ee) Compliance with OFAC.

(i) Neither the Company nor any of its subsidiaries, nor any director, officer or employee thereof, nor to the Company's knowledge, any agent, Affiliate or other person acting on behalf of the Company or any of its subsidiaries, is an individual or entity ("**Covered Person**") that is, or is owned or controlled by a Covered Person that is: (i) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("**OFAC**"), the United Nations Security Council ("**UNSC**"), the European Union ("**EU**"), His Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), nor (ii) located, organized, or resident in a country or territory that is the subject of a U.S. government embargo (including, without limitation, Cuba, Iran, North Korea, Syria and the Crimea).

(ii) The Company will not, directly or indirectly, use the proceeds from this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Covered Person: (i) to fund or facilitate any activities or business of or with any Person that, at the time of such funding or facilitation, is the subject of Sanctions, or in any country or territory that, at the time of such funding or facilitation, is the subject of a U.S. government embargo; or (ii) in any other manner that will result in a violation of Sanctions by any Covered Person (including the Agent).

(iii) For the past five (5) years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any direct or indirect dealings or transactions with any Covered Person that at the time of the dealing or transaction is or was the subject of Sanctions or any country or territory that, at the time of the dealing or transaction is or was the subject of a U.S. government embargo.

(ff) Company's Accounting System. The Company and its subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included in or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as described in the Registration Statement and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(gg) Disclosure Controls. The Company and its subsidiaries maintain an effective system of "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company has carried out evaluations of the effectiveness of its disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act.

(hh) Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "**Sarbanes-Oxley Act**") applicable to the Company as of the date hereof, including Section 402 related to loans and Section 302 and 906 related to certifications.

(ii) Compliance with Environmental Laws. The Company and its subsidiaries (i) are in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole. There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(jj) ERISA. (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), for which the

Company or any member of its “Controlled Group” (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Code, and, for the avoidance of doubt, when any provision of this Agreement relates to a past event or period of time, such definition shall include an organization that was, as of the time of such past event or period of time, a member of such group) would have any liability (each, a “**Plan**”) has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code, except for noncompliance that would not reasonably be expected to result in a material adverse effect on the Company and its subsidiaries, taken as a whole, (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan, excluding transactions effected pursuant to a statutory or administrative exemption, that would reasonably be expected to result in a material adverse effect on the Company and its subsidiaries, taken as a whole, (iii) no Plan is subject to Section 412 of the Code or Section 302 of ERISA, (iv) no “reportable event” (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur that either has resulted, or would reasonably be expected to result, in material liability to the Company, (v) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA, and (vi) there is no pending audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other governmental agency or any foreign regulatory agency with respect to any Plan that would reasonably be expected to result in a material adverse effect on the Company and its subsidiaries, taken as a whole. None of the following events has occurred or is reasonably likely to occur: (A) a material increase in the aggregate amount of contributions required to be made to all Plans by the Company in the current fiscal year of the Company compared to the amount of such contributions made in the Company's most recently completed fiscal year; or (B) a material increase in the “accumulated post-retirement benefit obligations” (within the meaning of Statement of Financial Accounting Standards 106) of the Company compared to the amount of such obligations in the Company’s most recently completed fiscal year.

(kk) Intellectual Property. The Company and its subsidiaries own or possess valid and enforceable rights to use all inventions, patents, trademarks, service marks, trade names, trade dress, domain names, goodwill associated with the foregoing, copyrights, know-how, trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures (including all registrations and applications for registration of the foregoing, as applicable) (collectively, “**Intellectual Property**”) used in or necessary for the conduct of its business as currently conducted or as currently proposed to be conducted. To the Company’s knowledge, the conduct of the business of the Company and its subsidiaries as currently conducted does not infringe, misappropriate or otherwise violate any Intellectual Property rights of others in any material respect, and to the knowledge of the Company, the conduct of its business as proposed to be conducted will not infringe, misappropriate or otherwise violate any Intellectual Property rights of others in any material respect. Except as described in the Registration Statement and the Prospectus or as would not reasonably be expected, individually or in the aggregate, to have a material adverse effect, there is no pending or, to the Company’s knowledge, threatened, action, suit, proceeding or claim by others (i) that the Company or any of its subsidiaries infringes, misappropriates or otherwise violates the Intellectual Property of others, or (ii) challenging the validity, enforceability, scope or ownership of any Intellectual Property owned by or licensed to the Company or its subsidiaries or their rights therein. To the knowledge of the Company, except as described in the Registration Statement and the Prospectus, no third party has infringed, misappropriated or otherwise violated any Intellectual Property owned by or exclusively licensed to the Company or its subsidiaries in any material respect. None of the Intellectual Property used by the Company or its subsidiaries in the conduct of its business has been obtained or is being used by the Company or its subsidiaries in material violation of any contractual obligation binding on the Company or any of its subsidiaries. To the

knowledge of the Company, (i) no third party has any ownership right in or to any Intellectual Property that is owned or purported to be owned by the Company or any of its subsidiaries, other than any co-owner of a patent or patent application within the Intellectual Property who is listed on the records of the U.S. Patent and Trademark Office (the "USPTO") as co-owner of such patent or named in such patent application; (ii) no third party has any ownership right in or to any Intellectual Property that is owned or purported to be owned by the Company or any of its subsidiaries, in any field of use, other than the respective licensor to the Company of such Intellectual Property or co-owners pursuant to the foregoing clause (i); and (iii) except as disclosed in the Registration Statement and the Prospectus, no government funding, facilities or resources of a university, college, other educational institution or research center was used in the development of any Intellectual Property that is owned or purported to be owned by the Company or its subsidiaries that would confer any governmental agency or body, university, college, other educational institution or research center any claim or right of ownership to any such Intellectual Property. The Company is not aware of any specific facts that would support a finding that any of the issued or granted patents owned by or licensed to the Company are invalid or unenforceable and, to the knowledge of the Company, all such issued or granted patents are valid and enforceable. The Company is not subject to any judgment, order, writ, injunction or decree of any court or any federal, state, local, foreign or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, or any arbitrator, nor has it entered into or is it a party to any agreement made in settlement of any pending or threatened litigation, which materially restricts or impairs its use of any Intellectual Property. The Company and its subsidiaries have taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of all Intellectual Property the value of which to the Company and its subsidiaries is contingent upon maintaining the confidentiality thereof, and no such Intellectual Property has been disclosed other than to employees, representatives, independent contractors, collaborators, licensors, licensees, agents and advisors of the Company and its subsidiaries, all of whom are bound by written obligations to maintain the confidentiality thereof. All founders, key employees and any other employees involved in the development of Intellectual Property for the Company and its subsidiaries have signed confidentiality and invention assignment agreements with the Company pursuant to which the Company either (I) has obtained ownership of and is the exclusive owner of, or (II) has obtained a valid and unrestricted right to exploit, sufficient for the conduct of its business, such Intellectual Property. To the knowledge of the Company, the persons who have prosecuted granted patents and who are prosecuting patent applications owned by or licensed to the Company or its subsidiaries have complied with their duty of candor and disclosure to the USPTO in connection with such patents or applications. The Company expects the products and processes described in the Registration Statement and the Prospectus as under development by the Company and its subsidiaries to fall within the scope of the claims of one or more patents or patent applications owned by or licensed to the Company or its subsidiaries.

(ll) Listing. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Shares are registered pursuant to Section 12(b) or Section 12(g) of the Exchange Act and are listed on the Nasdaq Global Market, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Nasdaq Global Market, nor has the Company received any notification that the Commission or the Nasdaq Global Market is contemplating terminating such registration or listing.

(mm) Brokers. The Company is not a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or the Agent for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.

(nn) No Outstanding Loans or Other Indebtedness. Subsequent to the respective dates as of which information is given in each of the Registration Statement and the Prospectus, x) the Company and its subsidiaries have not incurred any material liability or obligation, direct or contingent, nor entered into any material transaction; xi) the Company has not purchased any of its outstanding capital stock, nor declared, paid or otherwise made any dividend or distribution of any kind on its capital stock other than as described in the Registration Statement and the Prospectus; and xii) there has not been any material change in the capital stock, short-term debt or long-term debt of the Company, except in each case as described in each of the Registration Statement and the Prospectus, respectively.

(oo) No Reliance. The Company has not relied upon the Agent or legal counsel for the Agent for any legal, tax or accounting advice in connection with the offering and sale of the Shares.

(pp) Agent Purchases**.** The Company acknowledges and agrees that the Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act, the Exchange Act and this Agreement, purchase and sell Common Shares for its own account while this Agreement is in effect.

(qq) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules is true, complete and correct.

(rr) Compliance with Laws. The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not result in a Material Adverse Change.

(ss) Cybersecurity. The Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "**Personal Data**" has the same meaning as the term "personal information," "personal data," or any similar information under any Privacy Law (defined below). To the Company's knowledge, there have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same.

(tt) Compliance with Data Protection Requirements. The Company and its subsidiaries are presently, and at all times have been, in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority (collectively, the "**Privacy Laws**"), internal policies and contractual obligations, each relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access,

misappropriation or modification (collectively, the "**Data Protection Requirements**"). To ensure compliance with the Data Protection Requirements, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "**Policies**"). The Company and its subsidiaries have at all times made all disclosures to individuals required by applicable Data Protection Requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable Data Protection Requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Data Protection Requirements, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Data Protection Requirement; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability by any regulatory body or governmental authority under any Privacy Law.

(uu) Forward Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) (a "**Forward-Looking Statement**") contained in the Registration Statement and the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(vv) Other Underwriting Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

Any certificate signed by an officer of the Company and delivered to the Agent or to counsel for the Agent in connection with this Agreement shall be deemed to be a representation and warranty by the Company to the Agent as to the matters set forth therein.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(o) hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) Sale of Securities. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(b) Mechanics of Issuances.

(i) Issuance Notice. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in Section 5(a) and Section 5(b) shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided, however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and

(B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) Method of Offer and Sale. The Shares may be offered and sold (A) in privately negotiated transactions with the consent of the Company; (B) as block transactions; or (C) by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clauses (A) and (B) above) the method of placement of any Shares by the Agent shall be at the Agent's discretion.

(iv) Confirmation to the Company. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) Settlement. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of Section 5, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").

(vi) Suspension or Termination of Sales. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; *provided, however*, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior

to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

(vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) Material Non-Public Information. Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.

(c) Fees. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to Section 3(b)(vi)) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

(d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus (as defined below) prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "**Blue Sky Survey**" or memorandum and a "Canadian wrapper," and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable fees and disbursements of the Agent's counsel, including the reasonable fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any;

(ix) all fees, expenses and disbursements relating to background checks of the Company's directors, director nominees and executive officers; (x) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show; and (xi) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) $75,000 in connection with execution of this Agreement, (B) $25,000 in connection with each Triggering Event Date (as defined below) involving the filing of a form 10-K on which the Company is required to provide a certificate pursuant to Section 4(o) and (C) $15,000 in connection with each other Triggering Event Date on which the Company is required to provide a certificate pursuant to Section 4(o).

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or, in the Company's sole discretion, (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an "**Interim Prospectus Supplement")**, such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act).

(b) Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, or any Free Writing Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its

reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) Amendments and Supplements to the Prospectus and Other Securities Act Matters If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 4(d) and 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Sections 4(d) and 4(f).

(d) Agent's Review of Proposed Amendments and Supplements Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), insofar as such proposed amendment or supplement relates to the Shares, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, and the Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) Use of Free Writing Prospectus. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").

(f) Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Agent's consent. The Company shall furnish to the Agent, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that

subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; *provided, however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent.

(g) Filing of Agent Free Writing Prospectuses. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

(h) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(i) Blue Sky Compliance. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of

(or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof at the earliest possible moment.

(j) Earnings Statement. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act; *provided* that the Company will be deemed to have furnished such statement to its security holders and the Agent to the extent such statement is filed with Commission on EDGAR or any successor system.

(k) Listing; Reservation of Shares. (a) The Company will maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.

(l) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(m) Due Diligence. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.

(n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(o) Deliverables at Triggering Event Dates; Certificates. The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing

amended financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "**Triggering Event Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o) dated as of the date that the instructions for the sale of Shares are issued.

(p) Legal Opinions. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, a negative assurances letter and the written legal opinion of Cooley LLP, counsel to the Company, Latham & Watkins LLP, counsel to the Agent, and Barnes & Thornburg LLP, intellectual property counsel to the Company, each dated the date of delivery, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

(q) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause Ernst & Young LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in

form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent in connection with any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements; provided, that, such comfort letter shall not be required to be delivered to the Agent unless and until the Company delivers an Issuance Notice that is effective on or after the date of occurrence of such material transaction or event. Subject to the preceding sentence, the Company shall be required to furnish no more than one comfort letter hereunder per calendar quarter.

(r) Secretary's Certificate. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.

(s) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(t) Investment Limitation. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(u) Market Activities. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its Affiliates to, comply with all applicable provisions of Regulation M under the Exchange Act ("**Regulation M**"). If the limitations of Rule 102 of Regulation M (**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall cause each of its Affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply. The Company shall promptly notify the Agent if it no longer meets the requirements set forth in Section (d) of Rule 102.

(v) Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, (i) offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares or securities convertible into or exchangeable for

Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, (ii) effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding Common Shares, Shares; (iii) submit or file any registration statement under the Securities Act in respect of any Common Shares (other than as contemplated by this Agreement with respect to the Shares), or (iv) publicly announce the intention of doing any of the foregoing, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice; and will not directly or indirectly enter into any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be required in connection with the Company's (i) issuance or sale of Common Shares, options to purchase Common Shares or Common Shares issuable upon the exercise of options or other equity awards pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under the Principal Market rules or other compensation plan of the Company or its subsidiaries, as in effect on the date of this Agreement, (ii) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other equity awards outstanding at the date of this Agreement, and (iii) modification of any outstanding options, warrants of any rights to purchase or acquire Common Shares.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

(a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

(i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(p), Section 4(q) and Section 4(r).

(ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.

(iii) Material Adverse Changes. Except as disclosed in the Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.

(iv) No Suspension of Trading in or Delisting of Common Shares; Other Events The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or the FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York, authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

(b) Documents Required to be Delivered on each Issuance Notice Date. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President, Chief Financial Officer or General Counsel of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(c) No Misstatement or Material Omission. Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Time of Sale Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state

statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, and to reimburse the Agent and each such officer, employee and controlling person for any and all expenses (including the reasonable and documented fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in Section 6(b) below. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption “Plan of Distribution” in the Prospectus, and to reimburse the Company and each such director, officer and controlling person

for any and all expenses (including the reasonable and documented fees and disbursements of counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

(c) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission to so notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the Agent (in the case of counsel for the indemnified parties referred to in Section 6(a) above), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) Settlements. The indemnifying party under this Section 6 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such

indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(e) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); *provided, however,* that no additional notice shall be required with respect to any action for which notice has been given under Section 6(c) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this Section 6(e), the Agent shall not be required to contribute any amount in excess of the agent fees received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(e), each officer and employee of the Agent and each person, if any, who controls the Agent within the

meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

(a) Term. Subject to the provisions of thisSection 7, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this Section 7.

(b) Termination; Survival Following Termination.

(i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.

(ii) In addition to the survival provision ofSection 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. MISCELLANEOUS

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8-K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its respective Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(d) Notices. All communications hereunder, unless otherwise specified, shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC
520 Madison Avenue
New York, NY 10022
Facsimile:
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92129
Facsimile: (858) 523-5450
Attention: Michael E. Sullivan

If to the Company:
Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713

Facsimile: (919) 806-1146
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Cooley LLP
55 Hudson Yards
New York, NY 10001
Facsimile: (212) 479-6000
Attention: Jason Kent

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(d).

(e) Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 6, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "successors" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

(f) Partial Unenforceability. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

(g) Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings

herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Immediately Follows]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

CHIMERIX, INC.

By: */s/ Michael T. Andriole*
Name: Michael T. Andriole
Title: President and Chief Executive Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By: */s/ Donald Lynaugh*
Name: Donald Lynaugh
Title: Managing Director

EXHIBIT A

ISSUANCE NOTICE

[Date]

Jefferies LLC
520 Madison Avenue
New York, New York 10022

Attn: [_____]

Reference is made to the Open Market Sale Agreement between Chimerix, Inc. (the "**Company**") and Jefferies LLC (the "**Agent**") dated as of February 29, 2024. The Company confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)): _____

Issuance Amount (equal to the total Sales Price for such Shares):

$_____

Number of days in selling period: _____

First date of selling period: _____

Last date of selling period: _____

Settlement Date(s) if other than standard T+2 settlement:

_____

Floor Price Limitation (in no event less than $1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent's sole discretion): $ ____ per share.

Comments: _____

_____

By: _____
Name:
Title:

Schedule A

Notice Parties

The Company

Michael T. Andriole (mandriole@chimerix.com)

Michelle LaSpaluto (mlaspaluto@chimerix.com)

Michael Alrutz (malrutz@chimerix.com)

The Agent

Donald Lynaugh (dlynaugh@jefferies.com)

Michael Magarro (mmagarro@jefferies.com)

CHIMERIX

CHIMERIX.COM

December 27, 2023

Re: Member of the Board of Directors of Chimerix, Inc.

Dear Ms. Decker:

It is my sincere pleasure, on behalf of Chimerix, Inc. ("Chimerix"), to offer you a position as a member of the Board of Directors (the "Board") of Chimerix. Your appointment to the Board is contingent and effective upon your formal acceptance of this offer, which shall be evidenced by you signing below.

As compensation for your service as a member of the Board, you will receive a $40,000 annual retainer, and you will be eligible for additional cash retainer fees to the extent you serve on one or more committees of the Board, as provided in the Company's Non-Employee Director Compensation Policy. You will also be granted a nonqualified stock option to purchase 100,000 shares of common stock pursuant to our 2013 Equity Incentive Plan (the "Plan"), at an exercise price equal to the closing price of Chimerix's common stock on the date of your appointment to the Board. One-third of the shares subject to this option will vest on the one-year anniversary of the date of grant and the balance of the shares will vest in a series of 24 equal monthly installments thereafter, such that the option will be fully vested on the third anniversary of the date of grant, subject to your continued service through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

At each annual stockholder meeting following which your term as a director continues, you will be entitled to receive a nonqualified stock option to purchase 60,000 shares of common stock pursuant to the Plan, which will vest and become exercisable over a one-year period following the date of grant, subject to your continued service through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

Chimerix will also reimburse you for reasonable out-of-pocket travel expenses incurred in connection with your attendance at Board meetings.

If the terms of this letter are acceptable to you and you agree to serve as a member of the Board, please sign and date this letter below and return it to us via PDF or facsimile, retaining a copy for your records.

Very truly yours,

Mike Andriole
President, Chief Executive Officer and Director
Chimerix, Inc.

Accepted and agreed:

/s/ Lisa L Decker

Lisa L. Decker

Date: 28DEC2023

2505 Meridian Parkway, Suite 100 Durham, NC 27713

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, 333-253494, 333-263131, and 333-270210) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of Chimerix, Inc., and
3. Registration Statement (Form S-3 No. 333-255810) of Chimerix, Inc.;

of our report dated February 29, 2024, with respect to the consolidated financial statements of Chimerix, Inc. included in this Annual Report (Form 10-K) of Chimerix, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 29, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE 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, 2023 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: February 29, 2024

/s/ Michael T. Andriole

Michael T. Andriole

President & Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michelle LaSpaluto, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 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: February 29, 2024

/s/ Michelle LaSpaluto

Michelle LaSpaluto

Chief Financial Officer

(Principal 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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael T. Andriole, as Principal Executive Officer of the Company, certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §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: February 29, 2024

/s/ Michael T. Andriole
Michael T. Andriole
President & Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Chimerix, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michelle LaSpaluto, as Principal Financial Officer of the Company, certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §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: February 29, 2024

/s/ Michelle LaSpaluto
Michelle LaSpaluto
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Chimerix, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

CHIMERIX, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of **CHIMERIX, INC.**, a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). This Policy shall replace and supersede the Company's Incentive Compensation Recoupment Policy effective as of September 23, 2016 (the "***Prior Policy***") with respect to all Incentive Compensation that is received by a Covered Officer on or after the Effective Date; for clarity, the Prior Policy shall continue to apply to any Incentive Compensation that is received by a Covered Officer prior to the Effective Date. Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange as required by the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had

a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange as required by the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. Notwithstanding anything to the contrary in any employment, equity plan, equity award, severance benefit plan, or other individual agreement applicable to a Covered Officer, any recoupment of compensation pursuant to this Policy shall not constitute an event, condition or action taken by the Company for purposes of a Covered Officer's resignation for "Good Reason" (or similar concept, each as may be defined in the applicable plan or agreement). The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or

advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of such members of the Board under applicable law or Company policy.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to, without duplication except as required by law, the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *