UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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

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 ☐

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 27, 2023, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 88,891,300.

CHIMERIX, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023

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Unless otherwise mentioned or unless the context indicates otherwise, as used in this prospectus, the terms “Chimerix,” “the Company,” “we,” “us” and “our” refer to Chimerix, Inc., a Delaware corporation. We have obtained a registered trademark for Chimerix® in the United States. All other trademarks or trade names referred to in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I - FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,118	$ 25,842
Short-term investments, available-for-sale	180,357	191,492
Accounts receivable	11	1,040
Prepaid expenses and other current assets	6,136	9,764
Total current assets	200,622	228,138
Long-term investments	22,514	48,626
Property and equipment, net of accumulated depreciation	248	227
Operating lease right-of-use assets	1,606	1,964
Other long-term assets	292	386
Total assets	$ 225,282	$ 279,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,502	$ 3,034
Accrued liabilities	13,008	17,381
Total current liabilities	15,510	20,415
Line of credit commitment fee	125	250
Lease-related obligations	1,344	1,819
Total liabilities	16,979	22,484
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 88,891,300 and 88,054,127 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	89	88
Additional paid-in capital	986,202	970,535
Accumulated other comprehensive loss, net	(625)	(337)
Accumulated deficit	(777,363)	(713,429)
Total stockholders' equity	208,303	256,857
Total liabilities and stockholders' equity	$ 225,282	$ 279,341

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Procurement revenue	$ —	$ 31,971	$ —	$ 31,971
Contract and grant revenue	11	503	271	503
Licensing revenue	—	81	49	536
Total revenues	11	32,555	320	33,010
Cost of goods sold	—	333	—	447
Gross profit	11	32,222	320	32,563
Operating expenses:				
Research and development	17,396	15,263	53,144	52,350
General and administrative	9,304	5,313	19,431	16,785
Total operating expenses	26,700	20,576	72,575	69,135
(Loss) income from operations	(26,689)	11,646	(72,255)	(36,572)
Other income:				
Interest income and other, net	2,703	199	8,321	182
Gain on sale of business, net	—	229,670	—	229,670
(Loss) income before income taxes	(23,986)	241,515	(63,934)	193,280
Income tax expense	—	153	—	153
Net (loss) income	(23,986)	241,362	(63,934)	193,127
Other comprehensive (loss) income:				
Unrealized gain (loss) on debt investments, net	188	31	(288)	(16)
Comprehensive (loss) income	$ (23,798)	$ 241,393	$ (64,222)	$ 193,111
Per share information:				
Net (loss) income, basic	$ (0.27)	$ 2.75	$ (0.72)	$ 2.21
Net (loss) income, diluted	$ (0.27)	$ 2.75	$ (0.72)	$ 2.17
Weighted-average shares outstanding, basic	88,620,666	87,634,888	88,500,813	87,388,624
Weighted-average shares outstanding, diluted	88,620,666	87,814,330	88,500,813	89,070,831

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2022	88,054,127	$ 88	$ 970,535	$ (337)	$ (713,429)	$ 256,857
Share-based compensation	—	—	4,363	—	—	4,363
Employee stock purchase plan purchases	308,000	1	356	—	—	357
RSU stock issuance	221,440	—	—	—	—	—
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	106	—	106
Net loss	—	—	—	—	(21,372)	(21,372)
Total comprehensive loss						(21,266)
Balance, March 31, 2023	88,583,567	$ 89	$ 975,254	$ (231)	$ (734,801)	$ 240,311
Share-based compensation	—	—	2,959	—	—	2,959
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	(582)	—	(582)
Net loss	—	—	—		(18,576)	(18,576)
Total comprehensive loss						(19,158)
Balance, June 30, 2023	88,583,567	$ 89	$ 978,213	$ (813)	$ (753,377)	$ 224,112
Share-based compensation	—	—	7,880	—	—	7,880
Employee stock purchase plan purchases	121,233	—	109	—	—	109
RSU stock issuance	186,500	—	—	—	—	—
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	188	—	188
Net loss	—	—	—	—	(23,986)	(23,986)
Total comprehensive loss						(23,798)
Balance, September 30, 2023	88,891,300	$ 89	$ 986,202	$ (625)	$ (777,363)	$ 208,303

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2021	86,884,266	$ 87	$ 953,782	$ (21)	$ (885,596)	$ 68,252
Share-based compensation	—	—	3,708	—	—	3,708
Exercise of stock options	34,406	—	102	—	—	102
Employee stock purchase plan purchases	383,981	—	555	—	—	555
RSU stock issuance	133,527	—	—	—	—	—
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	(52)	—	(52)
Net loss	—	—	—	—	(24,767)	(24,767)
Total comprehensive loss						(24,819)
Balance, March 31, 2022	87,436,180	$ 87	$ 958,147	$ (73)	$ (910,363)	$ 47,798
Share-based compensation	—	—	3,593	—	—	3,593
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	5	—	5
Net loss	—	—	—		(23,468)	(23,468)
Total comprehensive loss						(23,463)
Balance, June 30, 2022	87,436,180	$ 87	$ 961,740	$ (68)	$ (933,831)	$ 27,928
Share-based compensation	—	—	3,819	—	—	3,819
Exercise of stock options	236,673	1	506	—	—	507
Employee stock purchase plan purchases	151,274	—	305	—	—	305
RSU stock issuance	221,000	—	—	—	—	—
Comprehensive income:						
Unrealized gain on investments, net	—	—	—	31	—	31
Net income	—	—	—	—	241,362	241,362
Total comprehensive income						241,393
Balance, September 30, 2022	88,045,127	$ 88	$ 966,370	$ (37)	$ (692,469)	$ 273,952

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net (loss) income	$ (63,934)	$ 193,127
Adjustments to reconcile net loss to net cash used in operating activities **:**		
Depreciation of property and equipment	68	73
Amortization of debt issuance costs	201	166
Amortization of discount/premium on investments	(5,655)	83
Share-based compensation	15,204	11,120
Gain on sale of TEMBEXA	—	(229,670)
Gain on sale of investments	—	(1)
Gain on sale of property and equipment	(5)	—
Lease-related amortization	(66)	28
Changes in operating assets and liabilities:		
Accounts receivable	1,029	(468)
Inventories	—	(2,467)
Prepaid expenses and other assets	3,616	(1,687)
Accounts payable and accrued liabilities	(4,958)	2,817
Net cash used in operating activities	(54,500)	(26,879)
Cash flows from investing activities:		
Purchases of property and equipment	(89)	(72)
Proceeds from sale of property and equipment	5	—
Purchases of short-term investments	(72,224)	(11,310)
Purchases of long-term investments	(24,592)	—
Proceeds from sales of short-term investments	—	7,699
Proceeds from maturities of short-term investments	139,430	68,135
Proceeds from sale of TEMBEXA	—	233,984
Net cash provided by investing activities	42,530	298,436
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	608
Proceeds from employee stock purchase plan	465	860
Payments of debt issuance costs	(219)	(161)
Payment of note payable related to Oncoceutics acquisition	—	(14,000)
Net cash provided by (used in) financing activities	246	(12,693)
Net (decrease) increase in cash and cash equivalents	(11,724)	258,864
Cash and cash equivalents:		
Beginning of period	25,842	15,397
End of period	$ 14,118	$ 274,261

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

CHIMERIX, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

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 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 accompanying unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2022. In the opinion of the Company's management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented have been included. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the full year, for any other interim period or for any future year.

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 are tables that present information about certain assets measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements September 30, 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	$ 12,928	$ 12,928	$ —	$ —
Total cash equivalents	12,928	12,928	—	—
Short-term investments				
U.S. treasury securities	97,939	44,880	53,059	—
Commercial paper	58,447	—	58,447	—
Corporate bonds	23,971	—	23,971	—
Total short-term investments	180,357	44,880	135,477	—
Long-term investments				
U.S. treasury securities	22,514	3,939	18,575	—
Total long-term investments	22,514	3,939	18,575	—
Total assets	$ 215,799	$ 61,747	$ 154,052	$ —

	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.

Employee Retention Credit

Under the provisions of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), the Company was eligible for a refundable employee retention credit subject to certain criteria. The Company recognized a $2.0 million employee retention credit during the three months ended September 30, 2022 related to labor costs recognized during 2020 and 2021, which is recorded in prepaid expenses and other current assets. For the three months ended September 30, 2022, $1.5 million was recorded as a reduction to research and development expenses and $ 0.5 million was 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 Quarterly Report on Form 10-Q, 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, 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. The Company has no obligation to draw down any amount under the Credit Facility, and has not drawn down any amount as of September 30, 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.

Borrowings under the Credit Facility accrue interest at a floating per annum rate of the greater of (i) 1.50% above the Prime Rate (as defined below) and (ii) 4.75%. Prime Rate is defined as the rate of interest per annum published in The Wall Street Journal or any successor publication thereto as the "Prime Rate". If such rate of interest from The Wall Street Journal becomes unavailable, the "Prime Rate" shall mean the rate of interest per annum announced by the Lender as its prime rate in effect. In each case, in the event such prime rate is less than zero, such rate shall be deemed to be zero for purposes of the Loan Agreement. The Company must also pay an unused line fee equal to 0.25% per annum on the unused portion of the Credit Facility, payable quarterly in arrears. Upon the termination of the Loan Agreement for any reason prior to the Maturity Date, the Company will be required to pay to the Lender an early termination fee of $0.5 million. The Loan Agreement also requires the Company to pay the Lender a non-refundable commitment fee of $0.5 million, payable in four equal installments beginning on the Effective Date and each anniversary of the Effective Date thereafter until January 31, 2025. As of September 30, 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 September 30, 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.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued research and development expenses	$ 6,532	$ 6,691
Accrued compensation	3,912	6,438
Other accrued liabilities	2,564	4,252
Total accrued liabilities	$ 13,008	$ 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 (as defined below) 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 all gross profits associated with the sales of TEMBEXA made outside of the United States during the exclusivity period of TEMBEXA on a market-to-market basis; (iii) royalty payments equal to 20% of future gross profits of TEMBEXA made in the United States associated with volumes above 1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA; 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 the Asset Purchase Agreement, the Company recognized $ 11,000 and $0.2 million of contract revenue for support provided to Emergent for the three and nine months ended September 30, 2023, respectively. The Company recognized $36,000 of contract revenue for support provided to Emergent for the three and nine months ended September 30, 2022.

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 September 30, 2023, the Company has a deferred revenue balance of $0.1 million related to these grants. For the three months ended September 30, 2023, the Company recognized no grant revenue and for the nine months ended September 30, 2023, the Company recognized $30,000 of grant revenue. For the three and nine months ended September 30, 2022, the Company recognized $ 0.5 million 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 three months ended September 30, 2023, the Company recognized no license revenue related to this agreement and for the nine months ended September 30, 2023, the Company recognized approximately $58,000 of license revenue related

to this agreement. For the three and nine months ended September 30, 2022, the Company recognized approximately $ 0.1 million 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 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 three months ended September 30, 2022, the Company recognized $32.0 million of procurement revenue related to these agreements.

The remaining deliveries of treatment courses related to the PHAC Contract 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 three 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 September 30, 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.

Basic and Diluted Net Income (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. 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 three and nine months ended September 30, 2023. For the three and nine months ended September 30, 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.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. In addition to estimates discussed in other sections of this Quarterly Report on Form 10-Q, the most significant estimates in the Company's consolidated financial statements relate to the valuation of stock options and the valuation allowance for deferred tax assets resulting from net operating losses. These estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for

making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

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 debt investments (in thousands):

	September 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 24,004	$ —	$ (33)	$ 23,971
Commercial paper	58,517	1	(71)	58,447
U.S. treasury securities	120,975	—	(522)	120,453
Total investments	$ 203,496	$ 1	$ (626)	$ 202,871

	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):

	September 30, 2023					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 18,971	$ (33)	$ —	$ —	$ 18,971	$ (33)
Commercial paper	51,968	(71)	—	—	51,968	(71)
U.S. treasury securities	113,704	(521)	—	—	113,704	(521)
Total	$ 184,643	$ (625)	$ —	$ —	$ 184,643	$ (625)
Number of securities with unrealized losses		66		—		66

	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 September 30, 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 September 30, 2023 (in thousands):

Maturing in one year or less	$	180,357
Maturing after one year through two years		22,514
Total debt investments	$	202,871

Note 3. 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 September 30, 2023 was 2.84 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 $0.2 million for the three months ended September 30, 2023 and 2022 and approximately $ 0.5 million for the nine months ended September 30, 2023 and 2022.

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 September 30, 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 September 30, 2023 (in thousands):

Assets		
Operating lease right-of-use assets	$	1,606
Liabilities		
Operating lease short-term liabilities (recorded within Accrued liabilities)	$	624
Operating lease long-term liabilities (recorded within Lease-related obligations)		1,344
Total operating lease liabilities	$	1,968

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

Years Ending December 31,		**As of September 30, 2023**
2023		186
2024		759
2025		781
2026		467
Total future minimum rental payments	$	2,193
Less amount of lease payments representing interest		225
Total present value of lease payments	$	1,968

As of December 31, 2022, operating lease payments over the remainder of the lease terms were as follows (in thousands):

Years Ending December 31,	As of December 31, 2022
2023	736
2024	759
2025	781
2026	467
Total future minimum rental payments	$ 2,743
Less amount of lease payments representing interest	351
Total present value of lease payments	$ 2,392

For the three months ended September 30, 2023 and 2022, the Company made lease payments of approximately $ 0.2 million and for the nine months ended September 30, 2023 and 2022, the Company made lease payments of approximately $0.5 million.

Significance of Revenue Source

The Company was the recipient of federal research contract funds from BARDA. Periodic audits are required in connection with the Company's receipt of such funds and certain costs may be questioned as appropriate by BARDA. Accordingly, at September 30, 2023 and December 31, 2022, the Company had recorded a provision for potential refundable amounts of $52,000.

Note 4. Equity Transactions and Share-based Compensation

At-The-Market Equity Offering; Shelf Registration Statement

On August 10, 2020, we entered into an Open Market Sale Agreement SM (the Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $75 million of shares of our common stock. As of August 9, 2023, the Form S-3 shelf registration statement that registered the shares of common stock available for sale under the 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 Jefferies Sales Agreement.

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. As of September 30, 2023, no sales have been made under the shelf registration statement.

Stock Options

The Company maintains a 2013 Equity Incentive Plan (the 2013 Plan), which provides for the grant of incentive stock options (ISOs), non-statutory 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. The number of shares of common stock reserved for future issuance automatically increased on January 1, 2023, by 4% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or 3.5 million shares. As of September 30, 2023, there was a total of 2.4 million shares reserved for future issuance under the 2013 Plan. The Company issued no shares of common stock pursuant to the exercise of stock options during the three and nine months ended September 30, 2023. The Company issued 237,000 shares and approximately 271,000 shares of common stock pursuant to the exercise of stock options during the three and nine months ended September 30, 2022.

Employee Stock Purchase Plan

The Company maintains a 2013 Employee Stock Purchase Plan (ESPP), which provides for the issuance of shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its designated affiliates. The Company has reserved a total of 4.8 million shares of common stock to be purchased under the ESPP, of which 2.2 million shares remained available for purchase as of September 30, 2023. The number of shares of common stock reserved for issuance automatically increased on January 1, 2023, by an additional 422,535 shares.

The ESPP 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. 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 Company issued approximately 121,000 and 429,000 shares of common stock pursuant to the ESPP during the three and nine months ended September 30, 2023. The Company issued approximately 151,000 and 535,000 shares of common stock pursuant to the ESPP during the three and nine months ended September 30, 2022, respectively. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option and were determined using a Black-Scholes option pricing model.

Restricted Stock Units

The Company has issued RSUs to certain employees 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. The Company issued 187,000 shares and approximately 408,000 of common stock pursuant to the vesting of RSUs during the three and nine months ended September 30, 2023. The Company issued 221,000 shares and approximately 355,000 shares of common stock pursuant to the vesting of RSUs during the three and nine months ended September 30, 2022.

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 share-based compensation expense recognized related to stock options, the ESPP and RSUs was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expense	$ 1,739	$ 2,097	$ 5,619	$ 5,827
General and administrative expense	6,141	1,722	9,585	5,293
Total share-based compensation expense	$ 7,880	$ 3,819	$ 15,204	$ 11,120

In December 2022, the Company announced a reduction in workforce. As a result, 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. The Company recorded expense ratably from the announcement date through the date of termination with approximately $0.4 million being recognized during the twelve months ended December 31, 2022 and an additional $0.6 million being recognized during the three months ended March, 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 three months ended March 31, 2023.

During the three months ended September 30, 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 period. This amount is recorded in general and administrative expenses.

Note 5. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2023 as the Company incurred losses for the nine month period ended September 30, 2023 and is forecasting an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2023. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method in accordance with FASB ASC 740.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company cannot currently support that realization of its deferred tax assets is more likely than not. However, the Company feels its deferred tax assets may be used upon the Company becoming profitable.

At September 30, 2023, the Company had no unrecognized tax benefits that would reduce the Company's effective tax rate if recognized.

Note 6. 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 over a possible 10-year period. 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 for delivery 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 assets 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 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 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 period under which the Company was contracted to provide the majority of operational support services to Emergent in furtherance of its obligations under the Asset Purchase Agreement and the BARDA Agreement concluded on March 26, 2023, except for certain services which the parties agreed would continue until the occurrence of a specific event, or in some cases a predetermined end date. The BARDA Agreement was novated to Emergent in December 2022. Under the Asset Purchase Agreement, the Company recognized approximately $11,000 and $0.2 million of contract revenue for support provided for the three and nine months ended September 30, 2023, respectively. The Company recognized $36,000 of contract revenue for support provided to Emergent for the three and nine months ended September 30, 2022.

The sale of TEMBEXA constitutes a significant disposition of a business, however, the Company determined the disposition did not represent a strategic shift, and accordingly, the Company did not account for the disposition as a discontinued operation. The Company recorded a $229.7 million net gain on sale of business in other income on the Consolidated Statement of Operations and Comprehensive (Loss) Income in the third quarter of 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 and July 2022. The Company recognized $9.3 million of procurement revenue under the Supply Agreement for the three months ended September 30, 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 USD $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 three months ended September 2022. Upon the assignment of the PHAC Contract to Emergent, which requires the consent of PHAC, if the remaining deliveries of treatment courses are made by Emergent, they will be subject to the royalty terms of the Asset Purchase Agreement applicable to gross profits outside the United States. 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 three months ended December 31, 2022.

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 7. 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. As of September 30, 2023, on the Consolidated Balance Sheets, the Company has recorded $15,000 of contract close-out costs in accrued liabilities and accounts payable.

These balances are expected to be fully paid by early 2024.

The following table summarizes the contract close-out costs (in thousands) recorded in 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 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 nine months ended September 30, 2023.

	Contract Close-out Costs
Balance at December 31, 2022	$ 1,311
Revised estimates	10
Payments	(250)
Balance at March 31, 2023	$ 1,071
Revised estimates	(122)
Payments	(96)
Balance at June 30, 2023	$ 853
Revised estimates	(79)
Payments	(759)
Balance at September 30, 2023	$ 15

For the three and nine months ended September 30, 2023, the revised accrual estimates resulted in a decrease to research and development expenses of $79,000 and $190,000, respectively.

Note 8. 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 three 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 in the fourth quarter of 2022.

The following table summarizes the restructuring charges (in thousands) recorded for the three 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 nine months ended September 30, 2023:

	Employee Termination Benefits
Balance at December 31, 2022	$ 1,442
Revised estimates	(73)
Payments	(641)
Balance at March 31, 2023	$ 728
Revised estimates	(89)
Payments	(395)
Balance at June 30, 2023	$ 244
Revised estimates	—
Payments	(92)
Balance at September 30, 2023	$ 152

Note 9. 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 September 30, 2023, and events which occurred subsequently but were not recognized in the financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (SEC) on March 2, 2023. Past operating results are not necessarily indicative of results that may occur in future periods.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item IA, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

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 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 - Enrollment on Target for Interim Data in 2025

The Phase 3 ACTION trial is enrolling in twelve countries including the United States, Canada, the United Kingdom, South Korea, Israel, Denmark, Germany, Italy, the Netherlands, Spain, Switzerland and Australia. Management expects interim overall survival (OS) and progression free survival (PFS) analyses from the trial to occur in 2025 with a final OS analysis 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. The first submission for marketing authorization would likely be initiated in the U.S. with submissions outside the U.S. to follow. In addition, in the event the result of the progression free survival analysis is

positive, we would discuss the potential for submission and an approval of ONC201 with regulatory authorities based on this data.

Publication of "*Clinical efficacy of ONC201 in H3K27M-mutant diffuse midline gliomas is driven by disruption of integrated metabolic and epigenetic pathways*"

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.

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. ONC206 dose escalation is expected to be completed in the first half of 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.

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. Prior to 2022, 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 the Asset Purchase Agreement, the Company recognized $11,000 and $0.2 million of contract revenue for expense reimbursement related to support provided to Emergent for the three and nine months ended September 30, 2023, respectively. The Company recognized $36,000 of contract revenue for support provided to Emergent for the three and nine months ended September 30, 2022.

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 September 30, 2023, the Company has a deferred revenue balance of $0.1 million related to these grants. For the three months ended September 30, 2023, the Company recognized no grant revenue and for the nine months ended September 30, 2023, the Company recognized $30,000 of grant revenue. For the three and nine months ended September 30, 2022, the Company recognized $0.5 million 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 three months ended September 30, 2023, the Company recognized no license revenue related to this agreement and for the nine months ended September 30, 2023, the Company recognized approximately $58,000 of license revenue related to this agreement. For the three and nine months ended September 30, 2022, the Company recognized approximately $0.1 million and $0.5 million, respectively, of license revenue related to this agreement.

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 three months ended September 30, 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 three months ended September 30, 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 three 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Direct research and development expenses	$ 11,024	$ 9,303	$ 32,925	$ 31,627
Research and development personnel costs - excluding stock-based compensation	3,648	3,177	12,101	13,200
Research and development personnel costs - stock-based compensation	1,739	2,097	5,619	5,827
Indirect research and development expenses	985	686	2,499	1,696
Total research and development expenses	$ 17,396	$ 15,263	$ 53,144	$ 52,350

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. 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.

Dociparstat Sodium (DSTAT)

The final clinical study report related to the Phase 3 DASH AML trial has been completed, submitted to the FDA, and the IND has been inactivated. No further clinical or regulatory action is anticipated. Additionally, we have approximately $15,000 of accounts payable and contract close-out accruals as of September 30, 2023, which we expect to be paid by early 2024.

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.

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 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 $7.9 million and $3.8 million was recognized in the three months ended September 30, 2023 and 2022, respectively, and $15.2 million and $11.1 million was recognized in the nine months ended September 30, 2023 and 2022, respectively. The increase in share-based compensation expense in 2023 was 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. The share-based compensation expense recognized included expense for stock options, RSUs and employee stock purchase plan purchase rights.

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

For performance-based RSUs, we begin to recognize the expense when it is deemed probable that the performance-based goal will be achieved. We evaluate the probability of achieving performance-based goals on a quarterly basis.

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 unaudited 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.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in Note 1 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 2, 2023. There have been no material changes during the nine months ended September 30, 2023 to our critical accounting policies, significant judgments and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

RESULTS OF OPERATIONS

Comparison of the Nine Months Ended September 30, 2023 and 2022.

The following table summarizes our results of operations for the nine months ended months ended September 30, 2023 and 2022, together with the changes in those items (in thousands except percentages):

	Nine Months Ended September 30,		Dollar Change	% Change
	2023	2022	Increase/(Decrease)	
Revenues:				
Procurement revenue	$ —	$ 31,971	$ (31,971)	(100.0) %
Contract and grant revenue	271	503	(232)	(46.1) %
Licensing revenue	49	536	(487)	(90.9) %
Total revenues	320	33,010	(32,690)	(99.0) %
Cost of goods sold	—	447	(447)	(100.0) %
Gross profit	320	32,563	(32,243)	(99.0) %
Operating expenses:				
Research and development	53,144	52,350	794	1.5 %
General and administrative	19,431	16,785	2,646	15.8 %
Total operating expenses	72,575	69,135	3,440	5.0 %
Loss from operations	(72,255)	(36,572)	(35,683)	97.6 %
Other income:				
Interest income and other, net	8,321	182	8,139	4,472.0 %
Gain on sale of business, net	—	229,670	(229,670)	(100.0) %
(Loss) income before income taxes	$ (63,934)	$ 193,280	$ (257,214)	(133.1) %
Income tax expense	—	153	(153)	(100.0) %
Net loss	$ (63,934)	$ 193,127	$ (257,061)	(133.1) %

Contract, Licensing and Procurement Revenue

For the nine months ended September 30, 2023, total revenue decreased to $0.3 million compared to $33.0 million for the nine months ended September 30, 2022. The decrease of $32.7 million is primarily related to a decrease in revenue related to the international TEMBEXA procurement agreements secured in 2022.

Research and Development Expenses

For the nine months ended September 30, 2023, our research and development expenses increased to $53.1 million compared to $52.4 million for the nine months ended September 30, 2022. The increase of $0.8 million primarily related to the following:

- an increase of $8.0 million primarily 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; offset by
- a decrease of $4.1 million in DSTAT development costs related to the discontinuation of the DSTAT program in 2022;
- a decrease of $1.6 million in the development of our other pipeline products, ONC206, ONC212, and CMX521; and
- a decrease of $1.2 million in compensation expenses.

General and Administrative Expenses

For the nine months ended September 30, 2023, our general and administrative expenses increased to $19.4 million compared to $16.8 million for the nine months ended September 30, 2022. The increase of $2.6 million primarily related to the following:

- an increase of $4.3 million in non-cash stock compensation 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 $1.7 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 nine months ended September 30, 2023, our interest income and other, net increased to income of $8.3 million compared to income of $182,000 for the nine months ended September 30, 2022. This increase is primarily attributable to interest earned on higher cash balances.

Gain on Sale of Business, Net

For the nine months ended September 30, 2022, we recorded a total of $229.7 million related to the net gain on the sale of the exclusive worldwide rights to brincidofovir, including TEMBEXA and specified related assets to Emergent.

Comparison of the Three Months Ended September 30, 2023 and 2022.

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022, together with the changes in those items (in thousands, except percentages):

	Three Months Ended September 30,		Dollar Change	% Change
	2023	2022	Increase/(Decrease)	
Revenues:				
Procurement revenue	$ —	$ 31,971	$ (31,971)	(100.0) %
Contract and grant revenue	11	503	(492)	(97.8) %
Licensing revenue	—	81	(81)	(100.0) %
Total revenues	11	32,555	(32,544)	(100.0) %
Cost of goods sold	—	333	(333)	(100.0) %
Gross profit	11	32,222	(32,211)	(100.0) %
Operating expenses:				
Research and development	17,396	15,263	2,133	14.0 %
General and administrative	9,304	5,313	3,991	75.1 %
Total operating expenses	26,700	20,576	6,124	29.8 %
(Loss) income from operations	(26,689)	11,646	(38,335)	(329.2) %
Other income:				
Interest income and other, net	2,703	199	2,504	1,258.3 %
Gain on sale of business, net	—	229,670	(229,670)	(100.0) %
(Loss) income before income taxes	$ (23,986)	$ 241,515	$ (265,501)	(109.9) %
Income tax expense	—	153	(153)	(100.0) %
Net (loss) income	$ (23,986)	$ 241,362	$ (265,348)	(109.9) %

Contract, Licensing and Procurement Revenue

For the three months ended September 30, 2023, total revenue decreased to $11,000 compared to $32.6 million for the three months ended September 30, 2022. The decrease of $32.5 million is primarily related to a decrease in revenue related to the international TEMBEXA procurement agreements secured in 2022.

Research and Development Expenses

For the three months ended September 30, 2023, our research and development expenses increased to $17.4 million compared to $15.3 million for the three months ended September 30, 2022. The increase of $2.1 million primarily related to the following:

- an increase of $2.5 million related to ONC201 research and development expenses, primarily in start-up expenses related to the ACTION Phase 3 study of ONC201 in patients who harbor the H3 K27M-mutation; offset by

- a decrease of $0.2 million in TEMBEXA expenses following the Asset Sale with Emergent in 2022.

General and Administrative Expenses

For the three months ended September 30, 2023, our general and administrative expenses increased to $9.3 million compared to $5.3 million for the three months ended September 30, 2022. The increase of $4.0 million primarily related to the following:

- an increase of $4.4 million in non-cash stock compensation 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 $0.6 million in legal and other operational expenses.

Interest Income and Other, Net

For the three months ended September 30, 2023, our interest income and other, net increased to $2.7 million compared to income of $199,000 for the three months ended September 30, 2022. This increase is primarily attributable to interest earned on higher cash balances.

Gain on Sale of Business, Net

For the three months ended September 30, 2022, we recorded a total of $229.7 million related to the net gain on the sale of the exclusive worldwide rights to brincidofovir, including TEMBEXA and specified related assets to Emergent.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2023, we had capital available to fund operations of approximately $217.0 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 September 30, 2023, we had an accumulated deficit of $777.4 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 the Jefferies Sales Agreement with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $75 million of shares of our common stock. As of August 9, 2023, the Form S-3 shelf registration statement that registered the shares of common stock available for sale under the 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 Jefferies Sales Agreement.

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. As of September 30, 2023, no sales have been made 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 September 30, 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.

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 period (in thousands):

	Nine Months Ended September 30,	
	2023	**2022**
Cash sources and uses:		
Net cash used in operating activities	$ (54,500)	$ (26,879)
Net cash provided by investing activities	42,530	298,436
Net cash provided by (used in) financing activities	246	(12,693)
Net (decrease) increase in cash and cash equivalents	$ (11,724)	$ 258,864

The table above sets forth the net decrease or increase in cash and cash equivalents alone and not the change in our total capital available to fund operations, which also includes short-term and long-term investments. Cash and cash equivalents includes cash on hand and securities with original maturities of 90 days or less.

Operating Activities

Net cash used in operating activities of $54.5 million for the nine months ended September 30, 2023 was primarily the result of our $63.9 million net loss and the change in operating assets and liabilities offset by the add-back of non-cash adjustments. The change in operating assets and liabilities includes a decrease of $5.0 million in accounts payable and accrued liabilities offset by a decrease in prepaid expenses and other assets of $3.6 million and a decrease in accounts receivable of $1.0 million. Non-cash expenses included add-backs of $15.2 million for share-based compensation and $0.2 million of amortization of deferred loan costs offset by $5.7 million of amortization of discount/premium on investments. Net cash used in operating activities of $26.9 million for the nine months ended September 30, 2022 was primarily the result of our $193.1 million net income, partially offset by the change in operating assets and liabilities and the add-back of non-cash adjustments. The change in operating assets and liabilities includes an increase in prepaid expenses and other assets of $1.7 million, an increase in inventories of $2.5 million and an increase in accounts receivable of $0.5 million, offset by a decrease of $2.8 million in accounts payable and accrued liabilities. Non-cash expenses included an add-back of $229.7 million for the gain on the sale of TEMBEXA offset by the add-back of $11.1 million for share-based compensation, $0.2 million of amortization of deferred loan costs and $0.1 million of amortization of discount/premium on investments.

Investing Activities

Net cash provided by investing activities of $42.5 million for the nine months ended September 30, 2023 was primarily the result of the maturity of $139.4 million in short-term investments, partially offset by the purchase of $72.2 million in short-term investments and the purchase of $24.6 million in long-term investments. Net cash provided by investing activities of $298.4 million for the nine months ended September 30, 2022 was primarily the result of $234.0 million of proceeds from the sale of TEMBEXA, the maturity of $68.1 million in short-term investments and the sale of $7.7 million in short-term investments, partially offset by the purchase of $11.3 million in short-term investments.

Financing Activities

Net cash provided by financing activities of $0.2 million for the nine months ended September 30, 2023 was primarily the result of $0.5 million in proceeds from stock purchases through our 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 nine months ended September 30, 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 in proceeds from the exercise of stock options and stock purchases through our ESPP.

MATERIAL CASH REQUIREMENTS

The discussion below summarizes our significant contractual obligations and commitments as of September 30, 2023.

Leases. See Note 3 of Notes to Consolidated Financial Statements included in this Quarterly Report on Form 10-Q 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 September 30, 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 3. 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% 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 certificates of deposit 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 certain 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 three and nine months ended September 30, 2023 and 2022.

ITEM 4. 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 (the Exchange Act)) as of September 30, 2023, has 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 officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

We routinely review our internal control over financial reporting and from time to time make changes intended to enhance the effectiveness of our internal control over financial reporting. We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal control over financial reporting on an ongoing basis and will take action as appropriate. There have been no changes to our internal control over financial reporting, as such term is defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act, during the third quarter of 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

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 that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading “Risk Factors” below.

- 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.
- If we obtain 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 rely on limited sources of supply for the drug components for each of our product candidates including ONC201, and any disruption in the chain of supply for either of these product candidates may cause delays in their development and commercialization.
- We routinely evaluate external assets to build our pipeline of product candidates and there can be no assurance that we will be successful in identifying or completing a transaction for a candidate, that any such transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.
- 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.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained elsewhere in this Quarterly Report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to Our Financial Condition and Need For Additional Capital

Except for the third quarter of 2022, we have incurred significant losses since our inception. 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 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 prior to 2022, including a net loss of $63.9 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of approximately $777.4 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 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 have not been 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 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 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, 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.

In September 2022, Silicon Valley Bank and the Company agreed to suspend the availability of future advances under the Loan Agreement until such time, if ever, the parties mutually agree to amend the Loan Agreement to, among other things, adjust the borrowing base and reset the covenants. We may never agree to such an amendment, and accordingly, we may not be able to rely upon the Loan Agreement as a viable source of future capital for our operations.

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

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

In early 2019, we initiated a review of external assets that could be added to our pipeline of product candidates. In January 2021, we acquired Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, including ONC201. In connection with this transaction, we are responsible for, and bear the future costs of, development and commercialization of the acquired compounds. These costs will be substantial, and we may require additional capital in order to pursue the development and commercialization of these compounds as planned. Moreover, the anticipated benefits of these transactions may never be realized due to the various risks and uncertainties associated with drug development detailed elsewhere in the risk factors. For example, in July 2019, we entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. pursuant to which we acquired exclusive worldwide rights to develop and commercialize Dociparstat Sodium (DSTAT) for any and all uses. In May 2022, we decided to discontinue the development of DSTAT and the License and Development Agreement was subsequently terminated.

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 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. Oncoceutic'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 most advanced clinical candidates, with respect to a potential approval for marketing. We may be required to conduct additional clinical, nonclinical or manufacturing validation studies and submit those data before 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 glioma before approval. Additional delays in the United States may result if any of our product candidates is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In the EU context, an Oral Explanation during MAA review could extend approval timelines and result in a Negative Opinion. A re-examination procedure is available in the EU whereby a Negative Opinion could be over-turned and become a Positive Opinion. New rapporteurs would be selected for the product. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates.

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

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

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

The authority for the FDA to award rare pediatric disease priority review vouchers for drugs that have received rare pediatric disease designation prior to September 30, 2024 currently expires on September 30, 2026. 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 will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. While the Inflation Reduction Act of 2022 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. Further, 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Such reform efforts are likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in a

litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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

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

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

While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, we may lose our rights and our competitors might be able to enter the market, which would have a material adverse effect on our business.

Risks Related to United States Government Contracts and Grants

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

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

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

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

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

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

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

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

Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.

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

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

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

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

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, during 2014, we were the target of an active and disruptive social media campaign related to a request for access to TEMBEXA. If we experience similar social media campaigns in the future, we may experience significant disruption to our business which could result in losses.

A possible consequence of both activism and legislation in this area is the need for us to initiate an unanticipated expanded access program or to make 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.

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 alternate providers that purport to supply ONC201, ONC206 or similar versions thereof and intend to take meaningful action to eliminate such alternative supplies when and if appropriate. In the event that patients opt to choose alternative 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 alternative 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. This decision could prompt adverse publicity or 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 initiation or 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 recently 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. Our future performance will depend, in part, on the successful integration of this management transition. If we do not successfully manage this transition, 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 September 30, 2023, 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. In the future, subject to limited exceptions, we will be 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 September 30, 2023, our then executive officers, directors, 5% stockholders (known to us through available information) and their affiliates beneficially owned approximately 25.6% 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.

Shareholder activism could cause material disruption to our business.

Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to financial restructuring, dividends, share repurchases and even sales of assets or the entire company.

For example, our shareholder Rubric Capital Management (Rubric) issued a press release and filed a Schedule 13D in November 2022, in which Rubric expressed a lack of confidence in the Company's strategic direction. In response, the Company issued a press release in which we stated we do not believe a liquidation of the Company is in the best interests of all of our shareholders as it would deprive them of the significant upside potential of ONC201 and our other assets. We also stated it would be irresponsible to patients with this deadly disease as it would halt critical progress on ONC201. We stated we are confident that the continued successful execution of our strategy is the best path to maximize shareholder value, and that our board and leadership team regularly consider all opportunities to create or enhance value.

Responding to proxy contests and other actions by activist investors could be costly and time-consuming, disrupt our operations and divert the attention of our board of directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.

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

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

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors

may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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 recently enacted 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. .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.

Our federal net operating loss (NOL) carryforwards 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. 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, processing) 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. Additionally, the California Consumer Privacy Act of 2018 (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 civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some protected health information processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, the California Privacy Rights Act of 2020 (CPRA) expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and 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). Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros 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.

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 (UK) 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 UK to the United States in compliance with law, such as the EEA, Switzerland, and UK's standard contractual clauses, 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 UK 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 UK 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 are quickly changing, becoming increasingly stringent, and creating regulatory 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); 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 phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), 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, 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.

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.

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 to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. 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; 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

The following exhibits are filed as part of this report:

Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation of the Registrant.
3.2[(2)]	Amended and Restated Bylaws of the Registrant.
4.1[(3)]	Form of Common Stock Certificate of the Registrant.
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

+ The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q 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 this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

(1) Incorporated by reference to the corresponding exhibit in Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867), filed with the SEC on April 16, 2013.

(2) Incorporated by reference to the corresponding exhibit in Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867), filed with the SEC on December 9, 2022.

(3) Incorporated by reference to the corresponding exhibit in Chimerix, Inc.'s Registration Statement on Form S-1 (No. 333-187145), as amended, filed with the SEC on March 27, 2013.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CHIMERIX, INC.

November 2, 2023

By: /s/ Michael T. Andriole

Michael T. Andriole

President and Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

Exhibit 31.1

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

I, Michael T. Andriole, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended September 30, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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. I have disclosed, based on my 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: November 2, 2023

/s/ Michael T. Andriole

Michael T. Andriole

President and Chief Executive Officer

(Principal Executive Officer and 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 Quarterly Report on Form 10-Q of Chimerix, Inc. (the "Company") for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael T. Andriole, as Principal Executive Officer and 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 Exchange Act; 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: November 2, 2023

/s/ Michael T. Andriole

Michael T. Andriole

President and Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.