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, 2022

OR

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

For the transition period from to

Commission file number: 001-35867

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** (Address of Principal Executive Offices)	**27713** (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 28, 2022, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 88,045,127.

CHIMERIX, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2022

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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® and TEMBEXA® 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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 274,261	$ 15,397
Short-term investments, available-for-sale	10,369	72,970
Accounts receivable	468	—
Inventories	—	2,760
Prepaid expenses and other current assets	6,022	4,678
Total current assets	291,120	95,805
Long-term investments	—	2,022
Property and equipment, net of accumulated depreciation	252	253
Operating lease right-of-use assets	2,078	2,404
Other long-term assets	430	56
Total assets	$ 293,880	$ 100,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,282	$ 2,788
Accrued liabilities	14,428	13,108
Note payable	—	14,000
Total current liabilities	17,710	29,896
Loan fees	250	—
Lease-related obligations	1,968	2,392
Total liabilities	19,928	32,288
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 88,045,127 and 86,884,266 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	88	87
Additional paid-in capital	966,370	953,782
Accumulated other comprehensive loss, net	(37)	(21)
Accumulated deficit	(692,469)	(885,596)
Total stockholders' equity	273,952	68,252
Total liabilities and stockholders' equity	$ 293,880	$ 100,540

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Procurement revenue	$ 31,971	$ —	$ 31,971	$ —
Contract and grant revenue	503	105	503	$ 1,928
Licensing revenue	81	2	536	5
Total revenues	32,555	107	33,010	1,933
Cost of goods sold	333	—	447	—
Gross profit	32,222	107	32,563	1,933
Operating expenses:				
Research and development	15,263	13,820	52,350	39,480
General and administrative	5,313	4,887	16,785	13,431
Acquired in-process research and development	—	—	—	82,890
Total operating expenses	20,576	18,707	69,135	135,801
Income (loss) from operations	11,646	(18,600)	(36,572)	(133,868)
Other income (loss):				
Interest income and other, net	199	40	182	130
Gain on sale of business, net	229,670	—	229,670	—
Income (loss) before income taxes	241,515	(18,560)	193,280	(133,738)
Income tax expense	153	—	153	—
Net income (loss)	241,362	(18,560)	193,127	(133,738)
Other comprehensive income (loss):				
Unrealized gain (loss) on debt investments, net	31	11	(16)	—
Comprehensive income (loss)	$ 241,393	$ (18,549)	$ 193,111	$ (133,738)
Per share information:				
Net income (loss), basic	$ 2.75	$ (0.21)	$ 2.21	$ (1.59)
Net income (loss), diluted	$ 2.75	$ (0.21)	$ 2.17	$ (1.59)
Weighted-average shares outstanding, basic	87,634,888	86,335,357	87,388,624	84,277,555
Weighted-average shares outstanding, diluted	87,814,330	86,335,357	89,070,831	84,277,555

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					
	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 (loss):						
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

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2020	62,816,039	$ 63	$ 785,673	$ —	$ (712,360)	$ 73,376
Share-based compensation	—	—	2,584	—	—	2,584
Exercise of stock options	710,132	1	3,529	—	—	3,530
Employee stock purchase plan purchases	259,837	—	330	—	—	330
RSU stock issuance	168,752	—	—	—	—	—
Issuance of common stock related to asset acquisition	8,723,769	9	43,436	—	—	43,445
Issuance of common stock, net of issuance costs of $7.2 million	13,529,750	13	107,829	—	—	107,842
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	(97,415)	(97,415)
Total comprehensive loss						(97,458)
Balance, March 31, 2021	86,208,279	$ 86	$ 943,381	$ (43)	$ (809,775)	$ 133,649
Share-based compensation	—	—	3,112	—	—	3,112
Exercise of stock options	41,465	—	119	—	—	119
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	32	—	32
Net loss	—	—	—	—	(17,763)	(17,763)
Total comprehensive loss						(17,731)
Balance, June 30, 2021	86,249,744	$ 86	$ 946,612	$ (11)	$ (827,538)	$ 119,149
Share-based compensation	—	—	3,431	—	—	3,431
Exercise of stock options	74,588	—	130	—	—	130
Employee stock purchase plan purchases	283,094	1	424	—	—	425
RSU stock issuance	241,000	—	—	—	—	—
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	11	—	11
Net loss	—	—	—	—	(18,560)	(18,560)
Total comprehensive loss						(18,549)
Balance, September 30, 2021	86,848,426	$ 87	$ 950,597	$ —	$ (846,098)	$ 104,586

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net income (loss)	$ 193,127	$ (133,738)
Adjustments to reconcile net income (loss) to net cash used in operating activities**:**		
Depreciation of property and equipment	73	143
Amortization of debt issuance costs	166	—
Amortization of discount/premium on investments	83	648
Share-based compensation	11,120	9,127
Fair value of common stock issued related to asset acquisition	—	43,445
Note payable related to asset acquisition	—	14,000
Gain on sale of TEMBEXA	(229,670)	—
Gain on sale of investments	(1)	(2)
Lease-related amortization	28	314
Changes in operating assets and liabilities:		
Accounts receivable	(468)	288
Inventories	(2,467)	(1,595)
Prepaid expenses and other assets	(1,687)	(2,005)
Accounts payable, accrued liabilities and deferred revenue	2,817	3,468
Net cash used in operating activities	(26,879)	(65,907)
Cash flows from investing activities:		
Purchases of property and equipment	(72)	(193)
Purchases of short-term investments	(11,310)	(105,355)
Purchases of long-term investments	—	(9,594)
Proceeds from sales of short-term investments	7,699	2,007
Proceeds from maturities of short-term investments	68,135	45,850
Proceeds from sale of TEMBEXA	233,984	—
Net cash provided by (used in) investing activities	298,436	(67,285)
Cash flows from financing activities:		
Proceeds from exercise of stock options	608	3,780
Proceeds from employee stock purchase plan	860	754
Proceeds from issuance of common stock, net of commissions	—	107,843
Payments of debt issuance costs	(161)	—
Payment of note payable related to asset acquisition	(14,000)	—
Net cash (used in) provided by financing activities	(12,693)	112,377
Net increase (decrease) in cash and cash equivalents	258,864	(20,815)
Cash and cash equivalents:		
Beginning of period	15,397	46,989
End of period	$ 274,261	$ 26,174

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

Note 1. The Business and Summary of Significant Accounting Policies

Description of Business

Chimerix is a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases.

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, 2021. 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, 2022 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.

Reclassifications

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

Fair Value of Financial Instruments

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

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

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

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

At September 30, 2022 and December 31, 2021, the Company had cash equivalents including money market funds and short-term investments, including U.S. Treasury securities, whose value is based on quoted market prices. At December 31, 2021, the

Company had long-term investments, including U.S. Treasury securities, whose value is based on quoted market prices. Accordingly, these securities are classified as Level 1.

At September 30, 2022, the Company had cash equivalents including commercial paper and short-term investments including commercial paper and corporate bonds and at December 31, 2021, the Company had short-term investments including U.S. Treasury securities, commercial paper and corporate bonds. As quoted prices are not available for these securities, they are valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security's credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

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

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

	Fair Value Measurements September 30, 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	$ 247,976	$ 247,976	$ —	$ —
Commercial paper	16,631	—	16,631	—
Total cash equivalents	264,607	247,976	16,631	—
Short-term investments				
U.S. treasury securities	1,989	1,989	—	—
Commercial paper	7,038	—	7,038	—
Corporate bonds	1,342	—	1,342	—
Total short-term investments	10,369	1,989	8,380	—
Total assets	$ 274,976	$ 249,965	$ 25,011	$ —

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

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) 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.

Prior to the sale of TEMBEXA to an affiliate of 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 (as defined below).

Employee Retention Credit

Under the provisions of the extension of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") passed by the United States Congress and signed by the President, the Company is eligible for a refundable employee retention credit subject to certain criteria. The Company recognized a $2.0 million employee retention credit during the three and nine 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 and nine months ended September 30, 2022, $1.5 million is recorded as a reduction to research and development expenses and $0.5 million is recorded as a reduction to general and administrative expenses. The Company has filed for refunds of the employee retention credits and as of the date of this Quarterly Report on Form 10-Q, it has not received any refunds and cannot reasonably estimate when it will receive any or all of the refunds.

Deferred Loan Costs

On January 31, 2022 (the Effective Date), the Company entered into a Loan and Security Agreement (the Loan Agreement), by and between the Company, as borrower, and Silicon Valley Bank, as the lender (the Lender). The Loan Agreement provides for a four-year secured revolving loan facility (the Credit Facility) in an aggregate principal amount of up to $50.0 million. Proceeds from the Credit Facility may be used for working capital and general corporate purposes. The Company has no obligation to draw down any amount under the Credit Facility, and has not drawn down any amount as of September 30, 2022.

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, 2022, 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 $0.3 million in other long-term assets on the Consolidated Balance Sheets. As of September 30, 2022, the Company has recorded a current loan fee liability of $0.2 million in accrued liabilities and a non-current loan fee liability of $0.3 million in loan fees on the Consolidated Balance Sheets.

In September 2022, in connection with the Asset Sale, Silicon Valley Bank 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.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued research and development expenses	$ 6,642	$ 4,642
Accrued compensation	4,791	5,491
Other accrued liabilities	2,995	2,975
Total accrued liabilities	$ 14,428	$ 13,108

Revenue Recognition

Policy

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

TEMBEXA Procurement Agreements

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 and nine months ended September 30, 2022, the Company recognized $32.0 million of procurement revenue related to these agreements.

Biomedical Advanced Research and Development Authority (BARDA)

In August 2022, the Company entered into the BARDA Agreement (as defined in Note 6 below), to deliver up to 1.7 million treatment courses of tablets and suspension formulations of TEMBEXA to the U.S. Government. On September 26, 2022, the Company sold TEMBEXA to Emergent in the Asset Sale.

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

Grant Revenue

Grant revenue under cost-plus-fixed-fee grants from the federal government and private foundations is recognized as allowable costs are incurred and fees are earned. At September 30, 2022, the Company has a deferred revenue balance of $0.2 million related to these grants. For the three and nine months ended September 30, 2022, the Company recognized $0.5 million of grant revenue and for the three and nine months ended September 30, 2021, the Company recognized $18,000 and $0.4 million of grant revenue related to these grants, respectively.

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, 2022, 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. 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. 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, 2021.

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 Issued Accounting Standards

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

Note 2. Investments

The following tables summarize the Company's debt investments (in thousands):

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 1,347	$ —	$ (5)	$ 1,342
U.S. treasury securities	2,008	—	(19)	1,989
Commercial paper	7,049	—	(11)	7,038
Total investments	$ 10,404	$ —	$ (35)	$ 10,369

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

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, 2022					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 1,342	$ (5)	$ —	$ —	$ 1,342	$ (5)
Commercial paper	4,807	(11)	—	—	4,807	(11)
U.S. treasury securities	1,989	(19)	—	—	1,989	(19)
Total	$ 8,138	$ (35)	$ —	$ —	$ 8,138	$ (35)
Number of securities with unrealized losses		5		—		5

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

The Company periodically reviews available-for-sale debt investments for other-than-temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company evaluates, among other things, the duration and extent to which the fair value of a security is less than its cost; the financial condition of the issuer and any changes thereto; and the Company's intent to sell, or whether it will more likely than not be required to sell, the security before recovery of its cost basis. At September 30, 2022, the Company did not intend to sell, and was not more likely than not to be required to sell, the available-for-sale debt investments in an unrealized loss position before recovery of the cost basis of the securities, which may be at maturity. There were no such declines in value for the three and nine months ended September 30, 2022 and 2021. Unrealized gains and losses on debt investments are recorded to unrealized (loss) gain on debt investments, net in the Consolidated Statements of Operations and Comprehensive Income (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 Income (Loss). The Company recognizes interest income on an accrual basis in interest income in the Consolidated Statements of Operations and Comprehensive Income (Loss).

The following table summarizes the scheduled maturity for the Company's debt investments at September 30, 2022 (in thousands):

Maturing in one year or less	$ 10,369
Total debt investments	$ 10,369

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, 2022 was 3.84 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 and $0.2 million, respectively, for the three months ended September 30, 2022 and 2021 and $0.5 million and $0.5 million for the nine months ended September 30, 2022 and 2021.

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, 2022, 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, 2022 (in thousands):

Assets		
Operating lease right-of-use assets	$	2,078
Liabilities		
Operating lease short-term liabilities (recorded within Accrued liabilities)	$	557
Operating lease long-term liabilities (recorded within Lease-related obligations)		1,968
Total operating lease liabilities	$	2,525

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

Years Ending December 31,		**As of September 30, 2022**
2022		180
2023		736
2024		759
2025		781
2026		467
Total future minimum rental payments	$	2,923
Less amount of lease payments representing interest		398
Total present value of lease payments	$	2,525

As of December 31, 2021, operating lease payments over the remainder of the lease terms were as follows (in thousands):

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

For the three months ended September 30, 2022 and 2021, the Company made lease payments of approximately $0.2 million and $0.1 million, respectively, and for the nine months ended September 30, 2022 and 2021, the Company made lease payments of approximately $0.5 million and $0.3 million, respectively.

Sublease

The Company subleased 3,537 square feet of its office space under a non-cancelable operating lease that expired in February 2021. For the three and nine months ended September 30, 2021, the Company recognized approximately $0 and $12,000 of income in Interest income and other, net on the Consolidated Statement of Operations and Comprehensive Loss. As this lease has terminated, there are no future minimum rentals payments to be received.

Significance of Revenue Source

The Company was the recipient of federal research contract funds from BARDA, the primary source of the Company's prior

year contract and grant revenue. 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, 2022 and December 31, 2021, the Company had recorded a provision for potential refundable amounts of $52,000.

Note 4. Equity Transactions and Share-based Compensation

Common Stock

On January 20, 2021, the Company entered into an underwriting agreement (the Underwriting Agreement) with Jefferies LLC and Cowen and Company, LLC, as representatives of the several underwriters named therein (collectively, the Underwriters), relating to the issuance and sale of 11,765,000 shares (the Shares) of the Company's common stock, par value $0.001 per share (the Common Stock). The price to the public in this offering was $8.50 per share, and the Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of $7.99 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to 1,764,750 additional shares of Common Stock at the public offering price. The net proceeds to the Company from this offering were approximately $107.8 million, as the Underwriters' option to purchase additional shares was exercised in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering closed on January 25, 2021.

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 increases on January 1 of each calendar year through January 1, 2023, by 4% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. On January 1, 2022, the common stock reserved for issuance under the 2013 Plan was automatically increased by 3.5 million shares. As of September 30, 2022, there was a total of 1.5 million shares reserved for future issuance under the 2013 Plan. The Company issued approximately 237,000 and 271,000 shares of common stock pursuant to the exercise of stock options during the three and nine months ended September 30, 2022. The Company issued approximately 75,000 and 826,000 shares of common stock pursuant to the exercise of stock options during the three and nine months ended September 30, 2021, respectively.

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 4.3 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, 2022. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year through January 1, 2023, by the lesser of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 422,535 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). On January 1, 2022, the common stock reserved for issuance under the ESPP was automatically increased 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 151,000 and 283,000 shares of common stock pursuant to the ESPP during the three months ended September 30, 2022 and 2021, respectively. The Company issued approximately 535,000 and 543,000 shares of common stock pursuant to the ESPP during the nine months ended September 30, 2022 and 2021, 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 approximately 221,000 and 355,000 shares of common stock pursuant to the vesting of RSUs during the three and nine months ended September 30, 2022. The Company issued approximately 241,000 and 410,000 shares of common stock pursuant to the vesting of RSUs during the three and nine months ended September 30, 2021.

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,	
	2022	2021	2022	2021
Research and development expense	$ 2,097	$ 1,853	$ 5,827	$ 4,995
General and administrative expense	1,722	1,578	5,293	4,132
Total share-based compensation expense	$ 3,819	$ 3,431	$ 11,120	$ 9,127

Note 5. Income Taxes

Provision for income taxes is based on the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Taxes calculated using the estimated annual effective tax rate	$ —	$ —	$ —	$ —
Discrete tax items	153	—	153	—
Provision for income taxes	$ 153	$ —	$ 153	$ —
Effective tax rate	0.06 %	— %	0.08 %	— %

Income taxes have been accounted for using the liability method in accordance with FASB ASC 740. The Company computes its interim provision for income taxes by applying the estimated annual effective tax rate method. The Company estimates an annual effective tax rate of 0.0% for the year ending December 31, 2022. This rate does not include the impact of any discrete items.

The Company's effective tax rate (ETR) from continuing operations was 0.06% and 0.08% percent for the quarter and nine months ended September 30, 2022, respectively, and 0.0% percent and 0.0% percent for the quarter and nine months ended September 30, 2021, respectively. During the third quarter and nine months ended September 30, 2022, the Company recorded an income tax expense of approximately $0.2 million as a result of the U.S. tax gain on the sale of business assets, which caused the quarterly and year-to-date ETR to be significantly different from the Company's historical annual ETR. The tax expense is composed of state current income taxes and is accounted for as a discrete tax item. The tax gain is fully consumed by existing U.S. federal NOLs and accordingly no federal income tax expense is recorded for the three and nine months ended September 30, 2022.

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. The anticipated taxable income for the year ended December 31, 2022 is a result of the gain from the sale of TEMBEXA and it is not expected that taxable income will recur in the foreseeable future. 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, 2022, 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. The BARDA Agreement consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). Under the terms of the BARDA Agreement, the base period activities are valued at approximately $127 million, consisting of an initial shipment of 319,000 treatment courses of TEMBEXA to be procured and shipped to the Strategic National Stockpile for an aggregate purchase price of approximately $115 million, and reimbursement for certain post-marketing activities of approximately $12 million. The options under the BARDA Agreement, which are exercised at the sole discretion of BARDA, are valued at approximately $553 million (if all such options are exercised during the 10-year contract period), which consists of options to purchase up to an additional 1.381 million treatment courses of TEMBEXA for an aggregate purchase price of approximately $551 million and funding for certain post-marketing activities of approximately $2 million. Upon the closing of the Asset Sale on September 26, 2022, the Company sold all its right, title, and interests to TEMBEXA to Emergent.

Emergent BioSolutions, Inc.

On September 26, 2022, the Company entered into a First Amendment to Asset Purchase Agreement (the Amendment) with Emergent, which amended its previously announced Asset Purchase Agreement, dated May 15, 2022 (the Original Purchase Agreement, and as amended by the Amendment, the Asset Purchase Agreement), with Emergent. The Amendment amended the Original Purchase Agreement to, among other things, update references to certain Contract Line Item Number (CLIN) references with respect to the milestone payments described below and update certain schedules to the Original Purchase Agreement.

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

The Company continues to provide operational support to Emergent in furtherance of the obligations under both the Asset Purchase Agreement (and related agreements) and the BARDA Agreement. The Company remains a party to the BARDA Agreement until such time as the BARDA Agreement is novated to Emergent, with its obligations subcontracted to Emergent until the novation occurs. The novation process is currently underway.

The sale of TEMBEXA constitutes a significant disposition of a business, however, the Company determined the disposition does not represent a strategic shift, and accordingly, the Company has not accounted for the disposition as a discontinued operation. The Company recorded a $229.7 million net gain on sale of business in other income (loss) on the Consolidated Statement of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 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 (Supply Agreement) with a third party outside of North America (Purchaser), pursuant to which the Company was responsible for supplying to the Purchaser, and the Purchaser was responsible for purchasing from the Company, TEMBEXA (brincidofovir) treatment courses for use outside of the United States.

Under the terms of the Supply Agreement, the Purchaser agreed to pay the Company an aggregate purchase price of approximately $9.3 million, in two equal installments. The first installment, $4.6 million, payable upon execution of the Supply Agreement, was received in June 2022. Deliveries pursuant to the international contract were completed in July 2022, which completed the contract delivery obligations and resulted in $4.7 million payment of the second installment of the purchase price in July 2022 and recognition of $9.3 million of procurement revenue for the three and nine 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 CAD $33.0 million ($25.3 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 and nine months ended September 30, 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.

BARDA 2011 Research and Development Contract

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

The fourth option segment ended on September 1, 2021 and the contract has expired in accordance with its terms. For the three and nine months ended September 30, 2021, the Company recognized revenue under this contract of $0.1 million and $1.6 million, respectively.

Cantex Pharmaceuticals, Inc.

In July 2019, the Company entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which the Company acquired exclusive worldwide rights to develop and commercialize, for any and all uses, a glycosaminoglycan compound known as DSTAT, which was being studied for the treatment of acute myeloid leukemia (AML). Under the terms of the license agreement, the Company is responsible for, and bears the future costs of, worldwide development and commercialization of DSTAT. Effective July 12, 2022, the Company terminated the License and Development Agreement.

SymBio Pharmaceuticals

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

In exchange for the license to SymBio for the Company's brincidofovir rights, the Company received an upfront payment of $5.0 million in October 2019. In connection with the Asset Sale, Chimerix's rights and obligations under the SymBio license agreement were transferred to Emergent. The Company could receive up to $12.5 million from Emergent in brincidofovir milestones related to the SymBio license agreement and will recognize corresponding revenue should any of the milestones be achieved.

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, 2022, on the Consolidated Balance Sheets, the Company has recorded $2.0 million of contract close-out costs in accrued liabilities and $0.3 million of contract close-out costs in accounts payable, which included additional expense of $0.9 million recorded to research and development expenses for the nine months ended September 30, 2022, on the Consolidated Statement of Operations after the decision to discontinue to the DSTAT program. These balances are expected to be fully paid over the next nine months.

The following table summarizes the contract close-out costs (in thousands) recorded for the nine months ended September 30, 2022:

	Contract Close-out Costs
Research & development	$ 926
General & administrative	8
Total contract close-out expenses	$ 934

The following table sets forth the accounts payable and accrual activity for contract close-out costs (in thousands) for the three months ended September 30, 2022.

	Contract Close-out Costs
Balance at June 30, 2022	$ 4,539
Revised estimates	$ (611)
Payments	$ (1,598)
Balance at September 30, 2022	$ 2,330

For the three months ended September 30, 2022, the revised accrual estimates resulted in a decrease to research and development expenses of $611,000.

Note 8. Oncoceutics Acquisition

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

whereupon the separate corporate existence of Merger Sub ceased, with Oncoceutics continuing as the surviving corporation of the Merger as a wholly-owned subsidiary of the Company.

As consideration for the Merger, the Company (a) paid an upfront cash payment of approximately $25.0 million, subject to certain customary adjustments, (b) issued an aggregate of 8,723,769 shares of the Company's common stock, (c) issued a promissory note to the Securityholders' Representative in the principal amount of $14.0 million (the Seller Note), to be paid in cash, subject to the terms and conditions of the Merger Agreement and the Seller Note, upon the one year anniversary of the closing of the Merger, and (d) agreed to make contingent payments up to an aggregate of $360.0 million based on the achievement of certain development, regulatory and commercialization events as set forth in the Merger Agreement, as well as additional tiered royalty payments based upon future net sales of ONC201 and ONC206 products, subject to certain reductions as set forth in the Merger Agreement, and a contingent payment in the event the Company receives any proceeds from the sale of a rare pediatric disease priority review voucher based on Oncoceutics' products. The promissory note totaling $14.0 million was paid to the Oncoceutics' shareholders in January 2022. A $20.0 million milestone payment was paid and expensed to research and development expenses in the fourth quarter of 2021 related to the achievement of the 20% ORR, evaluated by BICR, of ONC201 in H3 K27M-mutant glioma patients.

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

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

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

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

Note 9. 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, 2022, 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, 2021 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, 2021, filed with the Securities and Exchange Commission (SEC) on March 1, 2022. 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" 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 ONC201 which is in clinical-stage development for H3 K27M-mutant glioma as its lead indication. In addition, imipridone ONC206 is currently in dose escalating clinical trials.

Recent Developments

TEMBEXA (brincidofovir, BCV)

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

On August 26, 2022, we entered into a procurement contract (the BARDA Agreement) with the Biomedical Advanced Research and Development Authority (BARDA) for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA® to the U.S. government. The BARDA Agreement consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). Under the terms of the BARDA Agreement, the base period activities are valued at approximately $127 million, consisting of an initial shipment of treatment courses of TEMBEXA to be procured and shipped to the U.S. Government 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 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.

On September 26, 2022, we closed the Asset Sale with Emergent. In connection with the closing, we entered into a First Amendment to Asset Purchase Agreement (the Amendment) with Emergent. The Amendment amended the Asset Purchase Agreement to, among other things, update references to certain Contract Line Item Number (CLIN) references with respect to the milestone payments described below and update certain schedules to the Asset Purchase Agreement.

Upon closing of the Asset Purchase Agreement, we received $238 million upfront and could receive additional milestones of up to $136.5 million to be paid contingent upon execution of optional future procurement awards from BARDA and other development milestones. We may also earn a 20% royalty on future gross profit of TEMBEXA in the United States associated with volumes above 1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA. The agreement also allows us to earn a 15% royalty on all gross profit associated with TEMBEXA sales outside of the United States during the exclusivity period of TEMBEXA on a market-to-market basis.

We continue to provide operational support to Emergent in furtherance of the obligations under both the Asset Purchase Agreement (and related agreements) and the BARDA Agreement. We remain a party to the BARDA Agreement until such time as the BARDA Agreement is novated to Emergent, with our obligations subcontracted to Emergent until the novation occurs. The novation process is currently underway pursuant to the process specified by FAR Subpart 42.12.

TEMBEXA Procurement Agreements

On June 2022, we entered into a Supply Agreement (the Supply Agreement) with a third party outside of North America (the Purchaser), pursuant to which we were responsible for supplying to the Purchaser, and the Purchaser was responsible for purchasing from us, TEMBEXA (brincidofovir) treatment courses for use outside of the United States.

Under the terms of the Supply Agreement, the Purchaser agreed to pay us an aggregate purchase price of approximately $9.3 million, to be made in two equal installments. The first installment, payable upon execution of the Supply Agreement, was received in June 2022. Deliveries pursuant to the international contract were completed in July 2022, which completed the contract delivery obligations and resulted in $4.7 million payment of the second installment of the purchase price in July 2022 and recognition of $9.3 million of contract revenue for the three and nine months ended September 30, 2022.

Additionally, in June 2022, the Public Health Agency of Canada (PHAC) awarded a Contract (the PHAC Contract) to us, pursuant to which PHAC agreed to purchase up to approximately CAD $33.0 million ($25.3 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 contract revenue for the three and nine months ended September 30, 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.

Imipridones - ONC201, ONC206 and ONC212

Imipridones are a potential new class of selective cancer therapies. Clinical trials of ONC201 in glioma patients with the H3 K27M-mutation are underway at several locations in the U.S. ONC201 is an orally administered small molecule dopamine receptor D2 (DRD2) antagonist and caseinolytic protease (ClpP) agonist for the treatment of gliomas that harbor the H3 K27M mutation.

ONC201 - Phase 3 Study (the ACTION Study)

The ACTION study is a randomized, double-blind, placebo-controlled, multicenter international study in newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation. Treatment with ONC201 will occur shortly after completion of radiation therapy. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Activation of sites is expected to begin in November and continue into the first half of next year at up to 120 sites in North America, Europe and Asia Pacific. The first interim analysis is anticipated in early 2025 with final data in 2026.

Participants will be randomized to receive 625mg of ONC201 once per week, 625mg twice per week on two consecutive days, or placebo. The dose will be scaled by body weight for pediatric patients.

The primary endpoint of the study is overall survival (OS). The study will also evaluate progression free survival (PFS) with alpha control for both OS and PFS endpoints. OS will be assessed for efficacy at three alpha-allocated timepoints: 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 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.

Participants in the study must have a Karnofsky or Lansky performance status, a measure of patients' ability to perform ordinary tasks, of ≥70 at time of randomization. Key exclusion criteria are the presence of a primary spinal tumor, diffuse intrinsic pontine glioma, evidence of leptomeningeal spread of disease or cerebrospinal fluid dissemination. Stratification

factors include age (<21 years, ≥21 years), and an assessment of risk factors including tumor location, tumor size, and number of tumors.

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

In November 2021, a 50-patient analysis of ONC201 for the treatment of recurrent H3 K27M-mutant diffuse midline glioma was reported at the Society for Neuro-Oncology (SNO) Annual Meeting. Dual reader BICR determined an overall response rate (ORR) of 20% (95% Confidence Interval (CI): 10-34%) by Response Assessment in Neuro-Oncology Criteria for High Grade Gliomas (RANO-HGG). The median duration of response (mDOR) was 11.2 months (95% CI: 3.8 - not reached) in addition to the 8.3 month median time to response (mTTR). The disease control rate was 40%. PFS was 35% and 30% at 6 and 12 months, respectively, while OS was 57% and 35% at 12 and 24 months, respectively. In addition, best response by RANO-HGG and/or RANO Low Grade Gliomas (RANO-LGG) criteria, intended to account quantitatively for enhancing and non-enhancing disease, was 30% (95% CI: 18-45%). All serious adverse events were considered not related to ONC201 by sponsor assessment.

ONC206 and ONC212

ONC206 is a second generation imipridone that has demonstrated anti-cancer activity in pre-clinical models. ONC206 is currently being evaluated in Phase I dose escalation trials in partnership with the National Institutes of Health (NIH) and with the Pacific Pediatric Neuro-Oncology Consortium (PNOC). ONC206 is being considered for development in solid tumors, including potentially adrenal tumors, endometrial cancer and central nervous system (CNS) tumors.

ONC212, which targets GPR132 and ClpP, is in ongoing IND-enabling toxicology studies which are expected to be completed in late 2022 with a decision whether to enter clinical studies to be made in the first half of 2023. ONC212 is being explored pre-clinically in hematological malignancies, including AML, in collaboration with MD Anderson Cancer Center and in solid tumors, including pancreatic cancer, in collaboration with Brown University.

CMX521

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

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, issuing or transferring shares of common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that this review will result in the identification or consummation of any additional transaction 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.

TEMBEXA Procurement Agreements

In June 2022, we entered into a Supply Agreement (the Supply Agreement) with a third party outside of North America (the Purchaser), pursuant to which we were responsible for supplying to the Purchaser, and the Purchaser was responsible for purchasing from us, TEMBEXA (brincidofovir) treatment courses for use outside of the United States.

Under the terms of the Supply Agreement, the Purchaser agreed to pay us an aggregate purchase price of approximately $9.3 million, to be made in two equal installments. The first installment, payable upon execution of the Supply Agreement, was received in June 2022. Deliveries pursuant to the international contract were completed in July 2022, which completed the contract delivery obligations and resulted in a $4.7 million payment of the second installment of the purchase price in July 2022 and recognition of $9.3 million of procurement revenue for the three and nine months ended September 30, 2022.

Additionally, in June 2022, the Public Health Agency of Canada (PHAC) awarded a Contract (the PHAC Contract) to us, pursuant to which PHAC agreed to purchase up to approximately CAD $33.0 million ($25.3 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 and nine months ended September 30, 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.

BARDA

In February 2011, we entered into a cost-plus fixed fee development contract with BARDA. Under the contract we received $72.5 million in expense reimbursement and $4.6 million in fees. The contract expired in accordance with its terms in September 2021. Under the BARDA contract, we recognized revenue of $0.1 million and $1.6 million during the three and nine months ended September 30, 2021.

SymBio Pharmaceuticals

In September 2019, we entered into a license agreement with SymBio Pharmaceuticals (SymBio) for worldwide rights to develop, manufacture and commercialize TEMBEXA in all human indications, excluding the use for treatment of orthopoxviruses, including smallpox. In exchange for the license to SymBio for our TEMBEXA rights, we received an upfront payment of $5.0 million in October 2019. 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 and will recognize revenue should any of the milestones be achieved.

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

Research and Development Expenses

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

- fees paid to consultants and contract research organizations (CROs), including in connection with preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- salaries and related overhead expenses, which include stock option, restricted stock units and employee stock purchase program compensation and benefits, for personnel in research and development functions;

- payments to third-party manufacturers, which produce, test and package drug substance and drug product (including continued testing of process validation and stability);
- 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,	
	2022	2021	2022	2021
Direct research and development expenses	$ 9,303	$ 7,296	$ 31,627	$ 19,169
Research and development personnel costs - excluding stock-based compensation	3,177	4,081	13,200	13,171
Research and development personnel costs - stock-based compensation	2,097	1,853	5,827	4,995
Indirect research and development expenses	686	590	1,696	2,145
Total research and development expenses	$ 15,263	$ 13,820	$ 52,350	$ 39,480

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

TEMBEXA (Brincidofovir, BCV)

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

Imipridones program

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

Dociparstat sodium (DSTAT)

With the decision to stop development of DSTAT, we are currently in the process of closing our Phase 3 DASH AML trial. Due to the decision to terminate the program we have $2.3 million of accounts payable and contract close-out accruals as of

September 30, 2022. We expect the close-out activities related to this program to extend through mid-2023 as we continue treatment for enrolled patients on the trial and close down clinical trial sites.

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 $3.8 million and $3.4 million was recognized in the three months ended September 30, 2022 and 2021, respectively, and $11.1 million and $9.1 million was recognized in the nine months ended September 30, 2022 and 2021, respectively. 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, 2021 filed with the SEC on March 1, 2022. There have been no material changes during the nine months ended September 30, 2022 to our critical accounting policies, significant judgments and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

RESULTS OF OPERATIONS

Comparison of the Nine Months Ended September 30, 2022 and September 30, 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and September 30, 2021, together with the changes in those items (in thousands except percentages):

	Nine Months Ended September 30,		Dollar Change	% Change
	2022	2021	Increase/(Decrease)	
Revenues:				
Procurement revenue	$ 31,971	$ —	$ 31,971	*
Contract and grant revenue	503	1,928	(1,425)	(73.9)%
Licensing revenue	536	5	531	10,620.0 %
Total revenues	33,010	1,933	31,077	1,607.7 %
Cost of goods sold	447	—	447	*
Gross profit	32,563	1,933	30,630	1,584.6 %
Operating expenses:				
Research and development	52,350	39,480	12,870	32.6 %
General and administrative	16,785	13,431	3,354	25.0 %
Acquired in-process research and development	—	82,890	(82,890)	(100.0)%
Total operating expenses	69,135	135,801	(66,666)	(49.1)%
Income (loss) from operations	(36,572)	(133,868)	97,296	(72.7)%
Other income (loss):				
Interest income and other, net	182	130	52	40.0 %
Gain on sale of business, net	229,670	—	229,670	*
Income (loss) before income taxes	$ 193,280	$ (133,738)	$ 327,018	(244.5)%
Income tax expense	153	—	153	*
Net income (loss)	$ 193,127	$ (133,738)	$ 326,865	(244.4)%

*Not meaningful or not calculable

Contract, Licensing, and Procurement Revenue

For the nine months ended September 30, 2022, total revenue increased to $33.0 million compared to $1.9 million for the nine months ended September 30, 2021. The increase of $31.1 million is primarily related to the international TEMBEXA procurement agreements secured in 2022.

Cost of Goods Sold

For the nine months ended September 30, 2022, cost of goods sold was $0.4 million and for the nine months ended September 30, 2021 we did not record any cost of goods sold. The increase of $0.4 million is attributable to the international TEMBEXA procurement deliveries and the write-off of inventory deemed nonsalable.

Research and Development Expenses

For the nine months ended September 30, 2022, our research and development expenses increased to $52.4 million compared to $39.5 million for the nine months ended September 30, 2021. The increase of $12.9 million primarily related to the following:

- an increase of $15.6 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;
- an increase of $2.1 million for the development of our other pipeline products, ONC206, ONC212, and CMX521 which were partially offset from grant revenue; and
- an increase of $1.1 million in compensation expenses, of which $0.8 million relates to non-cash compensation to support development of our current pipeline; offset by

- a decrease of $3.1 million in DSTAT development costs related to the discontinuation of the DSTAT program; and
- a decrease of $2.2 million in brincidofovir development expenses following the approval of TEMBEXA in June 2021; and
- a decrease of $0.7 million in legal and other operational expenses.

General and Administrative Expenses

For the nine months ended September 30, 2022, our general and administrative expenses increased to $16.8 million compared to $13.4 million for the nine months ended September 30, 2021. The increase of $3.4 million primarily related to the following:

- an increase of $1.0 million in compensation, primarily related to non-cash stock compensation; and
- an increase of $2.3 million in legal and other operational expenses.

Acquired In-process Research and Development Expenses

In connection with our acquisition of Oncoceutics in January 2021, we recorded a total of $82.9 million of acquired in-process research and development expenses for the six months ended June 30, 2021, which included $25.0 million for an upfront payment to Oncoceutics, $43.4 million related to the fair value of the 8,723,769 shares of common stock issued to Oncoceutics, a $14.0 million promissory note due on the one-year anniversary of the acquisition and $0.3 million related to transaction costs consisting primarily of legal and professional fees.

Interest Income and Other, Net

For the nine months ended September 30, 2022, our interest income and other, net increased to income of $0.2 million compared to income of $0.1 million for the nine months ended September 30, 2021. This decrease is attributable to amortization of deferred loan costs and investment premium balances offsetting interest earned.

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, 2022 and September 30, 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and September 30, 2021, together with the changes in those items (in thousands, except percentages):

	Three Months Ended September 30,		Dollar Change	% Change
	2022	2021	Increase/(Decrease)	
Revenues:				
Procurement revenue	$ 31,971	$ —	$ 31,971	*
Contract and grant revenue	503	105	398	379.0 %
Licensing revenue	81	2	79	3,950.0 %
Total revenues	32,555	107	32,448	30,325.2 %
Cost of goods sold	333	—	333	*
Gross profit	32,222	107	32,115	30,014.0 %
Operating expenses:				
Research and development	15,263	13,820	1,443	10.4 %
General and administrative	5,313	4,887	426	8.7 %
Total operating expenses	20,576	18,707	1,869	10.0 %
Income (loss) from operations	11,646	(18,600)	30,246	(162.6)%
Other income (loss):				
Interest income and other, net	199	40	159	397.5 %
Gain on sale of business, net	229,670	—	229,670	*
Income (loss) before income taxes	$ 241,515	$ (18,560)	$ 260,075	(1,401.3)%
Income tax expense	153	—	153	*
Net income (loss)	$ 241,362	$ (18,560)	$ 259,922	(1,400.4)%

*Not meaningful or not calculable

Contract, Licensing, Procurement Revenue

For the three months ended September 30, 2022, total revenue increased to $32.6 million compared to $0.1 million for the three months ended September 30, 2021. The increase of $32.4 million is primarily related to the international TEMBEXA procurement agreements secured in 2022.

Research and Development Expenses

For the three months ended September 30, 2022, our research and development expenses increased to $15.3 million compared to $13.8 million for the three months ended September 30, 2021. The increase of $1.4 million primarily related to the following:

- an increase of $3.5 million related to ONC201 research and development expenses and start-up expenses related to the ACTION Phase 3 study of ONC201 in patients who harbor the H3 K27M-mutation; and
- an increase of $1.3 million in ONC206, ONC212, and CMX521 development expenses, some of which are partially offset from grant revenue; offset by
- a decrease of $2.8 million in DSTAT development costs related to the discontinuation of the DSTAT program; and
- a decrease of $0.6 million in compensation expenses.

General and Administrative Expenses

For the three months ended September 30, 2022, our general and administrative expenses increased to $5.3 million compared to $4.9 million for the three months ended September 30, 2021. The increase of $0.4 million primarily related to the following:

- an increase of $0.5 million in audit and tax fees and other operational expenses; offset by
- a decrease of $0.2 million in compensation expenses

Interest Income and Other, Net

For the three months ended September 30, 2022, our interest income and other, net increased to $199,000 compared to $40,000 for the three months ended September 30, 2021. 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, 2022, we had capital available to fund operations of approximately $284.6 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, 2022, we had an accumulated deficit of $692.5 million. We may continue to incur losses for the foreseeable future. The size of our losses will depend, in part, on the rate of future expenditures and our ability to generate revenues.

On August 10, 2020, we entered into an Open Market Sale Agreement℠ (the Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $75 million of shares of our common stock. Sales of our common stock made pursuant to the Jefferies Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 (File No. 333-244146), which was declared effective by the SEC on August 17, 2020. As of September 30, 2022, we have not sold any shares of our common stock under the Jefferies Sales Agreement.

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

On May 6, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC (the 2021 Shelf Registration Statement), which became effective upon filing, pursuant to which we registered for sale an unlimited amount of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. However, since we no longer qualify as a well-known seasoned issuer, on March 1, 2022, we filed two post-effective amendments to the 2021 Shelf Registration Statement 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 was declared effective by the SEC on May 2, 2022 and 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. The 2021 Shelf Registration Statement will remain in effect for up to three years from the date it initially became effective. As of September 30, 2022, 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. 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, 2022. In September 2022, in connection with the Asset Sale, Silicon Valley Bank 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,	
	2022	**2021**
Cash sources and uses:		
Net cash used in operating activities	$ (26,879)	$ (65,907)
Net cash provided by (used in) investing activities	298,436	(67,285)
Net cash (used in) provided by financing activities	(12,693)	112,377
Net increase (decrease) in cash and cash equivalents	$ 258,864	$ (20,815)

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 $26.9 million for the nine months ended September 30, 2022 was primarily the result of our $193.3 million net income 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 add-backs 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. Net cash used in operating activities of $65.9 million for the nine months ended September 30, 2021 was primarily the result of our $133.7 million net loss, partially offset by the change in operating assets and liabilities and the add-back of non-cash expenses. The change in operating assets and liabilities includes an increase of $3.5 million in accounts payable and accrued liabilities and a decrease in accounts receivable of $0.3 million, partially offset by an increase in prepaid expenses and other assets of $2.0 million and an increase in inventories of $1.6 million. Non-cash expenses included add-backs of $43.4 million for the fair value of common stock issued in relation to the Oncoceutics acquisition, $14.0 million for the note payable due on the one-year anniversary of the Oncoceutics acquisition, $9.1 million for share-based compensation, $0.1 million of depreciation of property and equipment and $0.6 million of amortization of discount/premium on investments.

Investing Activities

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. Net cash used in investing activities of $67.3 million for the nine months ended September 30, 2021 was primarily the result of the purchase of $105.4 million in short-term investments and the purchase of $9.6 million in long-term investments, partially offset by the maturity of $45.9 million in short-term investments and the sale of $2.0 million in short-term investments.

Financing Activities

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. Net cash provided by financing activities of $112.4 million for the nine months ended September 30, 2021 was primarily the result of $107.8 million in proceeds from the issuance of common stock and $4.5 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, 2022.

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.

Scientific Protein Laboratories LLC (SPL) Supply Purchase Obligation. Per a supply agreement with SPL, we are required to purchase an additional $2.4 million of DSTAT active pharmaceutical ingredient by December 31, 2023, unless this contract is terminated earlier commensurate with its termination provisions. Notice of termination has been provided, and termination will be effective November 27, 2022.

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, 2022, 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 and ONC206, in addition to royalties on product sales, we could be required to pay former Oncoceutics securityholders up to an aggregate of $340.0 million in remaining milestone payments, assuming the achievement of all remaining applicable milestone events under the merger agreement.
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, 2022 or September 30, 2021.

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, 2022, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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(f) and 15d-15(f) under the Exchange Act, during the third quarter of 2022 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 have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- We have only received regulatory approval for TEMBEXA, and all of our other product candidates are still under clinical development and may not obtain regulatory approval or be successfully commercialized.
- We may be unable to obtain, or may be delayed in obtaining, regulatory approval for 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.
- Even though we have obtained regulatory approval for TEMBEXA, or 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 we intend to rely on third parties to produce commercial supplies of any approved product candidates. We rely on limited sources of supply for the drug components for each of our product candidates including 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. For example, we may experience difficulties in integrating the operations of Oncoceutics into our business and in realizing the expected benefits of the merger with Oncoceutics.
- If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.
- If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, delays in the development of our product candidates, penalties and a loss of business.
- We face risks related to the coronavirus (COVID-19) outbreak, which could significantly disrupt our preclinical studies and clinical trials.

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 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. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 1, 2022.

Risks Related To Our Financial Condition and Need For Additional Capital

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

We are a biopharmaceutical company focused primarily on developing ONC201 for the treatment of H3 K27M-mutant glioma. We have incurred significant net losses in each year since our inception prior to 2022, including a net loss of $133.7 million for

the nine months ended September 30, 2021. As of September 30, 2022, we had an accumulated deficit of approximately $692.5 million.

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

- continue development and manufacturing activities related to imipridones, including ONC201 for the treatment of H3 K27M-mutant glioma, and other potential indications;
- obtain regulatory approvals for ONC201;
- scale-up manufacturing capabilities for ONC201;
- 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 have obtained regulatory approval and 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.

We achieved profitability in the third quarter of 2022 driven primarily through the closing of our Asset Sale with Emergent, however, 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 complete, and we may never generate the necessary data required to obtain regulatory approval and achieve product sales. Our anticipated development costs would likely increase if we do not obtain favorable results or if development of any product candidate is delayed. In particular, we would likely incur higher costs than we currently anticipate if development of any product candidate is delayed because we are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate, or we decide to conduct additional studies or trials for strategic reasons.

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

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

Our Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank, 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.

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

If we default under the credit facility, Silicon Valley Bank may accelerate all of our repayment obligations, which may require us to seek additional or alternate financing and/or modify our operational plans. We cannot guarantee that we will be able to comply with all of the covenants contained in the Silicon Valley Bank Loan Agreement in the future, or secure waivers if or when required. If we are unable to comply with or obtain a waiver of any noncompliance under the Loan Agreement, Silicon Valley Bank could declare an event of default or require us to further renegotiate the Loan Agreement on terms that may be significantly less favorable to us, or we may be required to seek additional or alternative financing. If we were to seek additional or alternative financing, any such financing may not be available to us on commercially reasonable terms or at all. If we are unable to access funds to meet those obligations or to renegotiate our agreement, Silicon Valley Bank could foreclose on our pledged assets and we would have to immediately cease operations. In addition, during the continuance of an event of default, the then-applicable interest rate on the then-outstanding principal balance is subject to increase. Upon an event of default, Silicon Valley Bank could also require us to repay the loan immediately, together with a prepayment penalty, and other fees. If we were to renegotiate the agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, Silicon Valley Bank's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Silicon Valley Bank of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our securities to decline.

In September 2022, in connection with the Asset Sale, Silicon Valley Bank 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 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. (Cantex) pursuant to which we acquired exclusive worldwide rights to develop and commercialize 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

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

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

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

We have not marketed, distributed or sold any products. Our most advanced product candidate is ONC201, which we are developing for the treatment of H3 K27M-mutant glioma. During the second half of 2022, as we work towards a potential accelerated approval for ONC201, we also plan to initiate a Phase 3 clinical study of ONC201, which could form the basis of regulatory approval.

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 candidates: 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 multiple clinical studies, and we plan to initiate a Phase 3 clinical study of ONC201 for H3 K27M-mutant glioma.

We have reached general agreement with the FDA on the design of the planned Phase 3 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.

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

Any delay in obtaining, or an inability to obtain, regulatory approvals could prevent us from generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for ONC201, 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

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

We do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our most advanced product candidates, including ONC201. 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.

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

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

Adverse events (AEs) caused by our product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. 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 comparison diagnostic test may be needed to identify patients with H3 K27M-mutant glioma before approval. Additional delays in the United States may result if any of our product candidates is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In the EU context, an Oral Explanation during MAA review could extend approval timelines and result in a Negative Opinion. A re-examination procedure is available in the EU whereby a Negative Opinion could be over-turned and become a Positive Opinion. New rapporteurs would be selected for the product. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates.

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

For ONC201, a standard of care diagnostic test is used to identify patients with H3 K27M-mutant glioma. FDA may require approval of a companion diagnostic in connection with an approval of ONC201 NDA. We intend to rely on third-parties for development of companion diagnostics for commercialization of ONC201, 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, if approved, do not meet the eligibility criteria for a priority review voucher.

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

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

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

The authority for the FDA to award rare pediatric disease priority review vouchers for drugs that have received rare pediatric disease designation prior to September 30, 2024 currently expires on September 30, 2026, although it is possible the FDA's authority to award rare pediatric disease priority review vouchers will be further extended through federal lawmaking. Absent

any such extension, if the NDA for ONC201 is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher.

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

Following regulatory approval for 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 we do not have experience in obtaining regulatory approval in any markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

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

Coverage and adequate reimbursement may not be available for ONC201, 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. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

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

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

- the federal healthcare anti-kickback statute which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the Federal Civil False Claims Act (False Claims Act) which permit private individuals to bring a civil action on behalf of the federal government to enforce certain of these laws thought civil whistleblower or *qui tam* actions and the Federal Civil Monetary Penalties Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the

federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, and their business associates as well as their covered subcontractors;
- the General Data Protection Regulation (GDPR), which impose obligations on companies in relation to the handling of personal data of individuals within the EU, along with related national legislation;
- mandated physician payments reporting laws and/or requirements throughout global jurisdictions, including EU member states, in which we conduct research and development and/or other business activities;
- the FDCA which prohibits, among other things, the adulteration or misbranding of drugs and devices;
- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies to report to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payers, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these or any other health regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and/or divert our management's attention from the operation of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they also may be subject to significant criminal, civil or administrative sanctions, including, but not limited to, exclusions from government funded healthcare programs, which could also materially affect our business.

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

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

For example, in March 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. However, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018 (the BBA), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increased in the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. Additionally, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and other litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. The FDA also released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services (DHHS) finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation (MFN) executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model on December 27, 2021, CMS published a final rule that rescinded the MFN model interim final rule. In July 2021, the Biden administration released an executive order with multiple provisions aimed at prescription drugs. In response to this executive order, in September 2021, DHHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions DHHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the other reform initiatives. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 into law, which among other things, (1) directs the U.S. Department of Health and Human Services 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. 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 Inflation Reduction Act of 2022 will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing U.S. Department of Health and Human Services to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be

implemented 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 such as the impact of the ongoing COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

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

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 (the "Asset Sale," as defined below) may not be realized fully or at all or may take longer to realize than expected.*

On May 15, 2022, we entered into an Asset Purchase Agreement (the Purchase Agreement) with Emergent BioSolutions Inc. (Emergent) for the sale of our TEMBEXA program and related assets (the Asset Sale). On September 26, 2022, the Asset Sale was completed.

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 Purchase Agreement. Under the terms of the Asset Purchase Agreement, 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. The milestones set forth in the 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.

Emergent may not adequately perform according to the terms of the BARDA Contract as a subcontractor prior to novation, or even following novation as a contractor, and we might be required to guarantee performance of all obligations that Emergent assumes under novation.

We remain primary on the BARDA contract until such time as the BARDA contract is novated to Emergent. In the event that we experience losses in connection with these contracts our business could be materially harmed.

Additionally, according to U.S. government contracting regulations, it is likely that the form of the novation agreement for the BARDA Contract will include a clause requiring that Chimerix guarantee Emergent's performance of the BARDA Contract. 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 depend on SymBio Pharmaceuticals for developing and commercializing TEMBEXA for human diseases other than orthopoxviruses, including smallpox.*

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.

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 Our 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 BARDA, the U.S. government has the power to unilaterally:

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

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

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

- FAR, and agency-specific regulations supplements to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts and implement federal procurement policy in numerous areas, such as employment practices, protection of the environment, accuracy and retention periods of records, recording and charging of costs, treatment of laboratory animals and human subject research;

- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

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

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

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

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

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

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

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

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

Risks Related to Our Business Operations and Industry

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

Recent media attention to individual patients' expanded access requests has resulted in the introduction of legislation at the local and national level referred to as "Right to Try" laws, such as the Right to Try Act, which are intended to give patients access to unapproved therapies. New and emerging legislation regarding expanded access to unapproved drugs for life-threatening illnesses could negatively impact our business in the future. In addition, during 2014, we were the target of an active and disruptive social media campaign related to a request for access to TEMBEXA. If we experience similar social media campaigns in the future, we may experience significant disruption to our business which could result in losses.

A possible consequence of both activism and legislation in this area is the need for us to initiate an unanticipated expanded access program or to make 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. We may also need to restructure or pause ongoing compassionate use and/or expanded access programs in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of our product candidates, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs.

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

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

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

We are highly dependent on the principal members of our executive team. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. To help attract, retain, and motivate qualified employees, we use share-based incentive awards such as employee stock options and restricted stock units. As of September 30, 2022, approximately 95.9% of all outstanding options had an exercise price above the closing price of the stock on that date. As a result, the current situation provides a considerable challenge to maintaining employee motivation, as well as creating a serious threat to retention until a recovery commences. If our share-based compensation ceases to be viewed as a valuable benefit, our ability to attract, retain, and motivate employees could be weakened, which could harm our results of operations.

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 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.

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

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

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

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

We may face disruptions that may affect our ability to initiate and complete clinical trials including disruptions in procuring items that are essential for our research and development activities, including, for example, raw materials used in the manufacturing of our product candidates and laboratory supplies for planned and ongoing clinical trials, in each case, for which there may be shortages because of ongoing efforts to address the outbreak. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring, data collection, data integrity and data analysis may be paused or delayed or negatively impacted due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. We may face manufacturing disruptions or disruptions related to the ability to obtain necessary institutional review board (IRB) or other necessary site approvals, as well as other delays at clinical trial sites.

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

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

We may experience difficulties in integrating the operations of Oncoceutics into our business or in integrating our TEMBEXA operations into the operations of Emergent and in realizing the expected benefits of the merger with Oncoceutics or the Asset Sale.*

The success of our merger with Oncoceutics (the Merger) will depend in part on our ability to realize the anticipated benefits from combining the operations of Oncoceutics with our business in an efficient and effective manner. Similarly, the success of the Asset Sale will depend in part on our and Emergent's ability to realize the anticipated benefits from combining our TEMBEXA related operations with Emergent's business in an efficient and effective manner. The respective integration processes could take longer than anticipated and could result in the loss of key employees, the disruption of each company’s ongoing businesses, tax costs or inefficiencies, or inconsistencies in standards, controls, information technology systems, procedures and policies, any of which could adversely affect our ability to achieve the anticipated benefits of the Merger or the Asset Sale, and could harm our financial performance and impair stockholder value. If we are unable to successfully or timely integrate the operations of Oncoceutics with our business, we may incur unanticipated liabilities and be unable to realize the revenue growth, synergies and other anticipated benefits resulting from the Merger, and our business, results of operations and financial condition could be materially and adversely affected.

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, including the impact of the ongoing COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

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

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

Based upon shares of common stock outstanding as of September 30, 2022, our then executive officers, directors, 5% stockholders (known to us through available information) and their affiliates beneficially owned approximately 35.9% of our voting stock. Therefore, these stockholders have the ability to substantially influence us through this ownership position. For example, these stockholders, if they choose to act together, may be able to influence the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Risks Related to Information Technology

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

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

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

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

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

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable laws and regulations. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise

to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

ITEM 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(1)	Amended and Restated Bylaws of the Registrant.
4.1(2)	Form of Common Stock Certificate of the Registrant.
10.1*	BARDA Agreement, dated August 26, 2022, by and between the Registrant and Biomedical Advanced Research and Development Authority
10.2	Amendment to BARDA Agreement, dated September 9, 2022, by and between the Registrant and Biomedical Advanced Research and Development Authority.
10.3*(3)	First Amendment to Asset Purchase Agreement, dated September 26, 2022, by and between the Registrant, Emergent BioSolutions Inc. and Emergent Biodefense Operations Lansing LLC.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive 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.
32.2	Certification of 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 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).

*Schedules and exhibits to the Agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

+ Certain confidential information contained in this exhibit, marked by brackets, has been omitted pursuant to Item 601 of Regulation S-K because the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to Registrant if publicly disclosed.

(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 Registration Statement on Form S-1 (No. 333-187145), as amended.

(3) Incorporated by reference to exhibit 2.1 in Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on September 28, 2022.

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 3, 2022 By: /s/ Michael A. Sherman
Michael A. Sherman
President and Chief Executive Officer
(Principal Executive Officer)

November 3, 2022 By: /s/ Michael T. Andriole
Michael T. Andriole
Chief Business and Financial Officer
(Principal Financial Officer)

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

Exhibit 10.1

AWARD/CONTACT	1. THIS CONTRACT IS RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES	
			1	51
2. CONTRACT *(Proc. Inst. Ident.)* NO. 75A50122C00047		3. EFFECTIVE DATE 08/29/2022	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. See Schedule	
5. ISSUED BY	CODE ASPR-BARDA	6. ADMINISTERED BY *(If other than Item 5)*	CODE	ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201
SCD-C

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, country, State and ZIP Code)*

CHIMERIX, INC. 1377270
MICHELLE LASPALUTO ;2505 MERIDIAN PKWY
2505 MERIDIAN PKWY
STE 100
DURHAM NC 27713

8. DELIVERY
☐ FOB ORIGIN ☒ OTHER *(See below)*

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶ ITEM G. 5

CODE 1377270 FACILITY CODE

11. SHIP TO/MARK FOR CODE
Multiple Destinations

12. PAYMENT WILL BE MADE BY CODE PSC
PSC
Program Support Center
7700 Wisconsin Ave
Bethesda MD 20814

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 3304 (a) (1)

14. ACCOUNTING AND APPROPRIATION DATA
See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
				15G. TOTAL AMOUNT OF CONTRACT ▶	$126,904,912.00

16. TABLE OF CONTENTS

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X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	11	X	J	LIST OF ATTACHMENTS	51
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. X CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. SEALED-BID AWARD (*Contractor is not required to sign this document.)* Your bid on Solicitation Number , including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)*

20A. NAME OF CONTRACTING OFFICER
JILL M. JOHNSON

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
CHIMERIX, INC. 1377270 BY s/ Michelle Laspaluto *(Signature of person authorized to sign)*	08/26/2022	BY /s/ Jill M. Johnson *(Signature of the Contracting Officer)*	08/26/2022

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STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR
CHIMERIX, INC. 1377270

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number:33-0903395 DUNS Number: 121785997 Smallpox Antiviral				
1	ASPR-22-01970 CLIN 0001 CPFF Base: Post Marketing Commitments, Suspension Manufacturing Scale-up and Other Stability Extension Support Obligated Amount: $[*] Requisition No: OS300891 Accounting Info: 2022.1992126.25103 Appr. Yr.: 2022 CAN: 1992126 Object Class: 25103 Funded: $[*]				[*]
2	ASPR-22-01970 CLIN 0002 FFP Base period: Delivery of FDP to the SNS Requisition No: OS300891 Accounting Info: 2022.1990178.25103 Appr. Yr.: 2022 CAN: 1990178 Object Class: 25103 Funded: $[*] Accounting Info: 2022.1992126.25103 Appr. Yr.: 2022 CAN: 1992126 Object Class: 25103 Funded: $[*]				[*]
3	CLIN 0003 Conduct of Ph 4 PMR Field Study Amount: $[*] (Option Line Item)				0.00
4	CLIN 0004 Delivery of FDP to the SNS Amount: $[*] (Option Line Item)				0.00
5	CLIN 0005 Delivery of FDP to the SNS Amount: $[*] (Option Line Item)				0.00
6	CLIN 0006 Delivery of FDP to the SNS Amount: $[*] (Option Line Item)				0.00
7	CLIN 0007 Delivery of FDP to the SNS Amount: $[*] (Option Line Item)				0.00

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

In 2004, the Department of Homeland Security (DHS) issued a Material Threat Determination for smallpox, establishing it as a threat to national security. Periodic smallpox outbreaks were common prior to the twentieth century with fatality rates of greater than thirty percent. Smallpox was eliminated as an endemic disease by 1980 following an intensive focused international ring vaccination campaign. The eradication of the disease led the scientific community to reduce the number of laboratories holding live variola virus so that at present the only known repositories of live variola virus are the World Health Organization (WHO) Collaborating Centers at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia and the State Center of Virology and Technology (VECTOR) in Novosibirsk, Russian Federation. While variola virus no longer exists in nature, the possibility of preserved, unrecognized samples or clandestine stocks, the potential re-emergence from natural sources, and recent advances in synthetic biology describing the construction of poxvirus genomes *de novo,* mean the threat of the reemergence of smallpox, although small, still exists.

Although the primary response to smallpox is the development and procurement of vaccines to break the chain of transmission, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) quickly recognized that in a smallpox attack many of those exposed to the virus would develop symptoms and become refractory to vaccination. A Department of Health and Human Services (HHS)-led collaboration between epidemiological modelers and subject matter experts resulted in the development of a public health consequence assessment for the number of primary and secondary infections after a deliberate large-scale release of smallpox in an urban setting. After substantial discussion over the refinement of the model, the scenario-based *Requirements for Smallpox Antivirals* were presented to the PHEMCE Enterprise Executive Committee (EEC) for approval describing a scenario requiring 1.7 million treatment courses of antivirals to mitigate the consequences of a large smallpox attack.

In March 2009, the Biomedical Advanced Research and Development Authority (BARDA) issued a Request for Proposals (RFP) under Project BioShield (PBS) to support the advanced development and procurement of 1.7 million treatment courses of a smallpox antiviral. An award under this solicitation resulted in the FDA approval of the first antiviral for the treatment of smallpox in 2018.

The development of antivirals against smallpox was deemed important and essential in the Institute of Medicine (IoM) report *Live Variola Virus, Considerations for Continuing Research* with the panel emphasizing the need for the development of multiple countermeasures with distinct mechanisms of action to obviate the potential for the evolution of viral resistance through selective pressure.
Additionally, developments in molecular biology since the Institute of Medicine report have increased the possibility of *de novo* synthesis of poxviruses genomes, leading to the possible creation of resistant virus and further emphasizing the danger of relying on a single therapeutic countermeasure. PBS funding will support the development and procurement of a second smallpox therapeutic with an alternative mechanism of action to address the potential for the development of resistance to the current stockpile drug.

B.1. PRICES / COSTS

The Base Period includes both a Cost-Plus Fixed Fee (CPFF) Contract Line Item Number (CLIN) to support completion of post marketing commitments, suspension manufacturing scale-up and stability extension support and a Firm Fixed Price (FFP) CLIN to support an initial procurement of final drug product (FDP) for delivery to the Strategic National Stockpile (SNS).

B.2.1. BASE PERIOD

a. The estimated cost of CLIN 0001 is $[*].

b. The fixed fee for CLIN 0001 is $[*]. The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in Section I of this contract.

c. The total estimated amount of CLIN 0001, represented by the sum of the estimated cost plus the fixed fee, is $11,878,478.

d. The firm fixed price amount of CLIN 0002 is $115,026,434.

e. The total contract value of CPFF and FFP CLINs 0001 and 0002 is $126,904,912.

Table 1. Base Period Cost Reimbursement CLIN

CLIN	Period of Performance	Supplies/Services	Estimated Cost	Fixed Fee	Cost + Fixed Fee (CPFF)
0001 (Base)	08/29/2022 – 08/28/2027	Post Marketing Commitments, Suspension Manufacturing Scale-up and Other Stability Extension Support	$[*]	$[*]	$11,878,478

Table 2. Base Period Firm Fixed Price CLIN

CLIN	Period of Performance	Supplies/Services	Units (Treatment Courses)	Unit Price ($)	Total ($)
0002 (Base)	08/29/2022 – 08/28/2027	Delivery of FDP to the SNS - Oral Solid Dosage Formulation - Liquid Formulation (Rebate-Prior Contract Costs)** Total	[*] [*] 319,000	[*] [*]	$ [*] $ [*] $ [*] $115,026,434

**See Rebates under Advanced Understandings in Section B.3 below.

B.2.2. OPTIONS

a. The contract includes optional cost reimbursement CLIN 0003 and optional Firm Fixed Price CLINs 0004, 0005, 0006 and 0007. The Government may exercise Options in accordance with 52.217-7 Option for Increased Quantity – Separately Priced Line Item (March 1989), as set forth

in Section I of the contract.

b. Unless the government exercises its option pursuant to the option clause contained in SECTION I, as well as successful completion of the "go criteria," the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in SECTION B.2 of the contract.

c. The Government may modify the contract bilaterally and require the contractor to provide supplies and services for Option Periods listed below, in accordance with 52.217-7.

d. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in Section B.3.j below. Specific information regarding the time frame for this notice is set forth in Section B.3.j . The tentative time frame for period of performance is set forth below.

e. As the government reserves the right to activate the option CLINs over a range of years, the pricing of the Option CLINs will vary to take inflation into consideration, as reflected in the Table 3. The final price per treatment course for the option CLINs will be the price identified for the fiscal year in which the CLIN is exercised, as laid out in Table 3.

Table 3. Option Period Pricing Based on Year of CLIN Activation

	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31
Tablet	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
Suspension	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]

Table 4. Option Period Cost Reimbursement CLIN

CLIN	Period of Performance	Supplies/Services	Estimated Cost	Fixed Fee	Cost + Fixed Fee (CPFF)
0003	estimated [*]	Conduct of Ph 4 PMR Field Study	$[*]	$[*]	$[*]

Table 5. Option Period Firm Fixed Price CLINs

CLIN	Period of Performance	Supplies/Services	Units (Treatment Courses)	Unit Price ($)*	Total ($)
0004	estimated [*]	Delivery of FDP to the SNS - Oral Solid Dosage Formulation - Liquid Formulation (Rebate-CLIN 0001 Costs)** Total	 [*] [*] [*]	 [*] [*]	 $ [*] $ [*] $ [*] $ [*]

0005	estimated [*]	Delivery of FDP to the SNS - Oral Solid Dosage Formulation - Liquid Formulation Total	 [*] [*] [*]	 [*] [*]	 $ [*] $ [*] $ [*]
0006	estimated [*]	Delivery of FDP to the SNS - Oral Solid Dosage Formulation - Liquid Formulation Total	[*] [*] [*]	 [*] [*]	 $ [*] $ [*] $ [*]
0007	estimated [*]	Delivery of FDP to the SNS - Oral Solid Dosage Formulation - Liquid Formulation Total	[*] [*] [*]	 [*] [*]	 $ [*] $ [*] $ [*]

*Pricing will be based on the year of the CLIN activation in accordance with Table 3.

**See Rebates under Advanced Understandings in Section B.3 below.

B.2.3. PAYMENT FOR FIRM FIXED PRICE CLINs

The Contractor will be entitled to receive payment under firm fixed price CLINs upon delivery and acceptance by the USG of any material or product delivered to the SNS.

B.3. ADVANCE UNDERSTANDINGS

a. Subcontracts and Consultants

Award of any FFP subcontract or FFP consulting agreement in excess of $250,000 or any cost reimbursement subcontract or consulting agreement under CPFF CLINs under this contract shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract or consulting agreement shall be provided to the Contracting Officer within ten (10) calendar days of full execution.

b. Site Visits, Inspections and General Audits

At the discretion of the USG, with two (2) business days' notice to the Contractor, the USG reserves the right to conduct site visits and inspections of activities under CPFF CLINs under this contract on an as needed basis, including collection of product samples and intermediates held by the Contractor, or subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the two-business days' notice to the Contractor.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, Contractor shall submit an issue report to the CO and COR within 15 business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the issues report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR within a time frame negotiated with the COR in writing after review of the issues report.

c. Man-in-Plant

At the discretion of the Government and with seven calendar (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor plant.

d. Emergency Use Authorization (EUA)

It is anticipated that the licensed therapeutic could be administered under an Expanded Access Investigational New Drug (EA IND) or under an "Emergency Use Authorization" (EUA) sponsored by BARDA and/or the Centers for Disease Control and Prevention (CDC) for an indication other than that for which it is licensed by the FDA. The Contractor will provide necessary supporting information and data per USG request to support USG regulatory filing for emergency preparedness, distribution, and use of the product. This may include but is not limited to the following: clinical and non-clinical data, the manufacturing facility, chemistry, manufacturing, and controls information, pharmacology and toxicology information, cross- reference authorization letter, including the right of reference to the information contained in Contractor's regulatory applications filed with the FDA. The Contractor shall support USG to address any FDA comments on the EA IND, pre-EUA, or EUA package, as applicable. If additional work is required, the parties will negotiate in good faith a modification to the Statement of Work to cover generation of any data required to support the USG's filing of an EA IND, pre-EUA, or EUA. USG will be responsible for submission and will work directly with FDA to seek authorization or licensure.

USG shall provide the Contractor with relevant product usage and distribution data or relevant patient treatment data collected under an EA IND or EUA, as such information is available and as legally able. Contractor understands that such data sharing may require an additional agreement with the sponsor of the EA IND or EUA. The Contractor shall maintain and update, as required by FDA, all required regulatory documentation (investigator brochure, regulatory binder, etc.) that will be used to support use under EA IND, pre-EUA, or EUA.

For information concerning EUA, please consult
https://www.fda.gov/RegulatoryInformation/Guidances/ucm125127 and

http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm

e. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and members of the PHEMCE, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

f. Overtime Compensation

No overtime (premium) compensation is authorized under the CPFF CLINs of the subject contract.

g. Contract Number Designation

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract as follows:

75A50122C00047

h. Quality Agreement

Within 30 (thirty) days of contract award, the Contractor, BARDA and SNS will develop a Quality Agreement that shall establish, define and document the responsibilities of both the Contractor and the USG (i.e., SNS and BARDA) for product shipping, receiving, and acceptance into the SNS. This document shall be drafted, approved, and signed by all parties prior to the commencement of product shipment and acceptance by the USG. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement.

i. Confidential Treatment of Sensitive Information

The Contractor shall, to the extent permitted by law, guarantee strict confidentiality of sensitive/confidential information/test results that are provided by the USG during the performance of the contract. The USG has determined that certain information/test results that the Contractor will be provided during the performance of the contract are of a sensitive nature.

Disclosure of confidential/sensitive information/test results, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the CO. Whenever the Contractor is uncertain with regard to the proper handling of information/ test results under the contract, the Contractor shall obtain a written determination from the CO.

Notwithstanding the foregoing, such information/test results shall not be deemed of a sensitive or confidential nature with respect to the Contractor for purposes of this Contract if such information/test results: (a) was already known to the Contractor other than by prior disclosure by the USG or discovered through work under a prior USG contract; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/test results by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the USG that controls such

information/test results not to disclose such information/test results to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/test results belonging to the USG.

The Contractor may disclose information/test results of a sensitive nature provided by the USG to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction (b) otherwise required by law or regulation, or (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/test results.

j. Understanding of Exercising of Option Period FFP CLINs

The schedule of delivery of the option period FFP CLINs will be determined during the modifications providing for the exercise of these options. If the USG does not intend to exercise an option in a fiscal year, USG will make a good faith effort to alert the Contractor in writing by December 30 of that fiscal year. USG will alert the Contractor in writing of the USG's intent to exercise an option at least 30 days prior to intended exercise of the option. The delivery schedules for the exercised option will be agreed to by the USG and Contractor. If the delivery schedule is greater than 30 months from the exercise of the option, USG reserves the right to renegotiate the price of the option period FFP CLIN to a lower cost per treatment course.

k. Rebates

In its invoicing under CLIN 0002, the Contractor will credit the USG for a fixed rebate amount of $[*] (stated in B.2.1 above). This is the amount that the USG reimbursed the Contractor under contract no. HHSO100201100013C, *Development of CMX001 For the Treatment of Smallpox,* for drug substance validation material and a post validation batch. In its invoicing under CLIN [*]. The amount stated in B.2.2 above is the minimum estimated rebate amount.

l. Order of Precedence for Timeline of Deliverables

Any inconsistency among the Contract and the incorporated attachments in Section J regarding the timeline of deliverables shall be resolved by giving precedence to the contract.

B.4. PROVISIONS CONCERNING ALLOWABLE COSTS

Notwithstanding the clause FAR 52.216-7, Allowable Cost and Payment, incorporated in this contract, the costs of the following items or activities shall be unallowable as direct costs under the CPFF CLINS of this contract unless authorized in writing in advance by the Contracting Officer:

a. Acquisition, by purchase or lease, of any interest in real property;
b. Rearrangement or alteration of facilities;
c. Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value;
d. Accountable Government Property, property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive

items" (defined as items of personal property, supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value;

e. Overtime;

f. Travel to attend general scientific meetings/conferences;

g. Foreign travel;

h. Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);

i. Costs to be paid for the performance of a fixed-price subcontract that exceeds $250,000;

j. Refreshments and meal expenditures;

k. Promotional items;

l. Printing;

m. Clinical trial insurance.

n. Patient care costs.

SECTION C – STATEMENT OF WORK

C.1. BACKGROUND AND PURPOSE

This contract is to procure a second approved smallpox antiviral for delivery to the Strategic National Stockpile (SNS) to achieve the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) smallpox preparedness requirement of having two readily available smallpox antivirals with distinct mechanisms of action. The scope of work for this contract (across the Base and Option periods) includes the manufacture and delivery of up to 1.7 Million Treatment Courses (TCs) of the smallpox antiviral TEMBEXA, comprising oral tablets and oral suspension formulation to the SNS and the associated activities to support these deliveries: Post Marketing Commitments, Suspension Manufacturing Scale-up, Stability Extension Support, and Conduct of a Phase 4 Field Study. The Procurement and R&D efforts for the TEMBEXA program will progress in specific stages that cover Base Periods and Option Periods as specified in this contract.

C.2. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, set forth in SECTION J – LIST OF ATTACHMENTS, attached hereto and made a part of this contract.

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. METHOD OF DELIVERY

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor's name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

D.2. FOB DESTINATION DELIVERIES

The Contractor shall describe the storage conditions for each product, specifically noting the acceptable temperature range required to maintain product quality. The Contractor shall be responsible for maintaining product temperature control until the product(s) arrives at the Strategic National Stockpile (SNS) and has completed product acceptance by the USG. The Contractor shall provide the Government with an ambient exposure letter that covers the time the product(s) leaves the Contractor's validated storage facility until arrival at the SNS. Upon Government acceptance of the product(s), the responsibility for temperature control shall transfer to the Government as well as the responsibility for logging ambient exposure time (temperatures between 8-25°C). The Contractor will provide and place TempTale(s) on each pallet of product while the product is inside the Contractor's validated storage facility prior to placing the product(s) onto the truck(s) of the designated carrier. The Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

For the purpose of this SECTION E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms, authorize any changes in the Statement of Work, modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The Contractor is advised to review FAR 52.243-1 Changes – Fixed Price Contracts Alternate V and FAR 52.243-2 Changes-Cost reimbursement contracts Alternative V, which are incorporated by reference into this contract in ARTICLE I.1.

Inspection and acceptance of reports will be performed at:

Office of Contract Management and Acquisition (CMA) Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services O'Neill House Office Building
Washington, DC 20515

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

- FAR 52.246-2, Inspection of Supplies-Fixed-Price (Aug 1996) – applicable to FFP CLINs
- FAR 52.246-7, Inspection of Research and Development – Fixed-Price (Aug 1996) – applicable to FFP CLINs
- FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984) – applicable to CPFF CLINs
- FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The contract will consist of a base period of five (5) years from the contract effective date. The period of performance may be extended with the exercise of option(s), structured as CLINs, as set forth in SECTION B, to a maximum of ten (10) years.

F.2. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work (see SECTION C and SECTION J) and upon delivery and acceptance of the items described in SECTION F.3 by the Contracting Officer or their duly authorized representative.

All product deliveries under FFP CLINs will adhere to the following. Upon delivery of the product at the agreed upon SNS location, the following procedures shall apply. The Government shall:

a. Inspect the shipment for accuracy against the bill of lading, inspect product containers for damage and retrieve data logging devices and data upon receipt;

b. Notify Contractor within 24 hours if there is any damage to packaging or if temperature as recorded on the data logging device(s) during Product shipment to the designated storage location exceeds shipping temperature specifications.

c. Within one business day notice of excursions or damage, the Contractor shall provide the government with further instructions on how to proceed or a certificate of compliance.

d. The government will complete all incoming inspections within three (3) business days of delivery or receipt of the aforementioned documents. If BARDA does not reject the Product within such three (3) day period, the Product shall be deemed accepted, subject to the government's rights under paragraph (k) of FAR 52.246-2, Inspection for supplies-Fixed Price.

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.1. Submission of Contract Deliverables

Documents shall be delivered electronically via email to the Contracting Officer (CO) and the Contracting Officer's Representative (COR). Additionally, the Contractor shall upload documents to the appropriate Government designated file sharing system. The Government will provide authorized log in access to the file share program to two Contractor representatives. Each representative must complete a mandatory training provided by the Government prior to gaining user access. A notification email shall be sent to the CO and COR upon electronic delivery of any documents.

F.3.2. Reporting Requirements and Other Deliverables

In addition to those reports required by other terms of this contract, the Contractor shall submit to the CO and the COR technical progress reports. These reports shall be subject to the technical inspection and requests for clarification by the COR. These reports shall be brief, factual, and prepared in accordance with the following formats:

1. Kick-off Meeting

The Contractor and Government shall conduct a kickoff meeting within 30 calendar days after contract award to review HHS procedures, processes, and expectations. Contractor shall provide an itinerary/agenda no later than two (2) business days before meeting. Contractor shall provide minutes from the kickoff meeting within seven (7) business days after the meeting.

2. Project Meeting Conference Calls, Agendas, and Meeting Minutes
A conference call between the Contract Officer (CO), the Contracting Officer's Representative (COR) and designees and the Contractor's Project Leader/delegate and designees shall occur biweekly or at a frequency determined by the CO and/or COR. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the COR. Electronic copy of conference call meeting agendas shall be provided via e-mail to the CO, COR, and uploaded into an agreed digital sharesite by the Contractor no later than two (2) business days before the conference call is held. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded into an agreed digital sharesite by the Contractor within seven (7) business days after the conference call is held.

3. Monthly Progress Report
This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th of each month following the end of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report. Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort. SECTION II Part A: SUMMARY - A

description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall
include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to the proposed progress,

effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

A Monthly Progress Report will not be required in the same month Annual Progress Reports or a Final Report are due.

4. Annual Progress Report
This report shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 30th calendar day following the end of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report. Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort. SECTION II Part A: SUMMARY - A

description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

An Annual Progress Report will not be required for the period when the Final Technical Report is due.

5. Draft Final Report and Final Report
These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report shall be due no later than forty-five (45) calendar days prior to the expiration date of the contract and the Final Report is due before the expiration date of the contract. The report shall be draft only in that BARDA comments have not been received/adjudicated and the report shall conform to the following format:

Title Page: The title for these reports shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e- mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report. Progress:

SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

SECTION II: RESULTS - A detailed description of the work performed and the results obtained including all expenses for the entire contract period of performance.

6. FDA/Regulatory Agency Correspondence, Meeting Summaries, and Submissions.
   a. The Contractor shall inform BARDA of all communications with the FDA for the orthopox

indications for this specific product, provide all communications and submissions related to the product, and provide previous correspondences with FDA related to the development of the therapeutic within five (5) business days of submission to or receipt from FDA.

b. The Contractor shall maintain and update, as required by the FDA, all required regulatory documentation (investigator brochure, regulatory binder, etc.), that will be used to support use under EUA and/or licensure.
c. The Contractor shall obtain FDA concurrence on the regulatory pathway to licensure for orthopox indications (i.e. traditional approval, accelerated approval, or Animal Rule), if applicable.
d. The Contractor shall conduct all necessary meetings with the FDA to support submission of an sNDA for orthopox indications to the FDA and endeavor to include BARDA staff, as silent observers, in all scheduled phone calls or face to face meetings with regulatory authorities, if applicable.
e. Within five business days of any informal meeting with the FDA, the Contractor shall forward the initial draft minutes to BARDA. The Contractor shall forward the final minutes when available and if applicable.
f. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. The Contractor shall provide BARDA with ten (10) business days, or as soon as possible in which to review and provide comments back to the Contractor prior to the Contractor's submission to the FDA. The Contractor shall address in writing all concerns raised by BARDA before FDA submission.
g. The Contractor shall re-label investigational product (upon licensure) to be consistent with the licensed product, in accordance with regulatory requirements. Within five (5) business days of any formal meeting with the FDA, the Contractor shall forward the initial draft minutes to BARDA. The Contractor shall forward the final minutes when available.
h. The Contractor shall notify the Contracting Officer's Representative and Contracting Officer within one (1) business day of all FDA arrivals to conduct site visits/audits by any regulatory agency. The Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.
i. The Contractor shall forward Standard Operating Procedures (SOPs) upon request from COR.
j. The Contractor shall provide raw data and/or specific analysis of data first produced in the performance of this contract with USG funds upon request from the COR.

7. Integrated Master Project Plan

The Contractor shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables and Work Breakdown Structure (WBS) elements. Attention shall be placed on providing sufficient turnaround time for the USG (BARDA, FDA, and CDC) for review of critical documentation. The Contractor shall integrate to demonstrate interdependencies among all CLINs. The Integrated Master Project Plan shall be incorporated into any potential contract and will be used to monitor performance of the contract. A Draft Plan shall be provided within 30 calendar days of contract

award and the Final Plan shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

- Critical Path Milestones
  The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.
- Work Breakdown Structure
  The Work Breakdown Structure (WBS) shall be discernable and consistent. BARDA may require the Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.
- Risk Mitigation Plan/Matrix
  The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template to be completed by any prospective Contractor. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

8. Technology Packages
   Technology packages developed under the contract including complete protocols must be submitted within 10 business days of request by the COR. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data.

9. Clinical and Nonclinical Study Protocols and Reports
   The Contractor shall submit to the COR Draft Protocols and associated study/experiment/test plans 30 days prior to study initiation prior to submission to regulatory agencies (IACUC, FDA, etc.). The Contractor shall submit to the COR Final Protocols 10 business days prior to the execution of the study or within 10 business days of request by the COR. Approval must be provided in writing by the COR prior to the execution of the study. Draft Reports are due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to the FDA. Final Reports are due 30 calendar days after receiving comments on the Draft Report. Final FDA submissions shall be provided to BARDA concurrently or no later than one (1) business day after submission to the FDA.

10. Raw Data and Data Analysis
    Contractor shall provide data or data analysis to the CO and COR within 20 business days of request, amend reports if required, and adjudicate all comments.

11. Annual/Final Invention Report
    All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. If

no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

12. Publications
    Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the COR for review prior to submission. Reports shall be submitted to the COR for review 30 calendar days for manuscripts and fifteen (15) calendar days for abstracts prior to intended publication or external submission.

13. Press Releases
    The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

14. Security Report
    The Contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products. Reports shall be due within 24 hours of an activity or incident.

15. Security Plan
    The Contractor shall provide a Security Plan within 90 days of contract award. The requirements for the Security Plan and general instructions are outlined in SECTION J, Attachment 6.

16. Manufacturing Plan
    The Contractor shall submit to the COR a comprehensive manufacturing plan for review and approval within 90 days of contract award.

17. Quality Management Systems Plan
    The Contractor shall submit to the COR a Quality Management System Plan for approval within 90 days of contract award.

F.3.3. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

The Contractor shall provide an Incident Report for any major developments or deviations that significantly impact the Contractor's ability to successfully meet objectives, deliverables or schedule (e.g., significant manufacturing deviations or loss, BSL-4 laboratory incidents, etc.). If any incident occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor, the Contractor shall:

- Within one (1) business day of notification of an incident, notify the CO and COR.
- Provide updates to the CO and COR within two (2) business days of additional developments.
- Submit within fifteen (15) business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If critical observations are found, submit a Corrective Action Plan within five (5) business days.
- Provide an Incident Report with critical observations within forty five (45) days of the incident.

F.3.4. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under the CPFF CLINs of this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA within 60 days of the audit or site visit. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the CO and COR within five (5) business days of completion of activities identified in any report.

F.3.5. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government related to activities funded under the CPFF CLINs of this contract with two (2) business days' advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 15 business days of the audit.
- CO and COR will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

F.3.6. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR. Contractor shall submit written justification of progress towards satisfying Go/No-Go criteria. CO/COR will provide a written response within 10 days.

F.3.7. DELIVERABLE SCHEDULE

Item No.	Description	Addresses	Deliverable Schedule
1	Kick-off Meeting	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of contract award. Meeting minutes are due no later than 7 (seven) business days following meeting.
2	Project Meeting Conference Call, Agendas and Meeting Minutes	CO: (1) electronic copy COR: (1) electronic copy	Meeting agendas are due no later than 2 (two) business days before each meeting. Meeting minutes are due no later than 7 (seven) business days following each meeting.
3	Monthly Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15th of each month following the end of each reporting period.
4	Annual Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30th calendar day following the end of each reporting period.
5	Draft Final Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due no later than 45 calendar days prior to the expiration date of the contract.
6	Final Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due before the expiration date of the contract.
7	FDA/Regulatory Agency Correspondence and Meeting Summaries	CO: (1) electronic copy COR: (1) electronic copy	Correspondence, meeting summaries, and reports are due within 5 (five) business days of each meeting or submission to or receipt from FDA/regulatory agency.
8	Integrated Master Project Plan - Critical Path Milestones	CO: (1) electronic copy	Draft Plan due within 30 days of contract award.

	- Work Breakdown Structure - Risk Mitigation Plan/Matrix	COR: (1) electronic copy	Final Plan due within 90 days of contract award. Updates due as requested by the COR.
9	Technology Packages	CO: (1) electronic copy COR: (1) electronic copy	Due within 10 business days of request by the COR.
10	Clinical and Nonclinical Study Protocols and Reports	CO: (1) electronic copy COR: (1) electronic copy	Draft Protocols due 30 days prior to study initiation. Final Protocols due 10 business days prior to execution of the study or within 10 business days of request by the COR. Draft Report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Final Report due 30 calendar days after receiving comments on the Draft Report. Final FDA submissions shall be provided to BARDA concurrently or no later than one (1) business day after submission to the FDA.
11	Raw Data and Data Analysis	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall provide data or data analysis to the CO and COR within 20 business days of request, amend reports if required, and adjudicate all comments.
12	Annual/Final Invention Report	CO: (1) electronic copy COR: (1) electronic copy	An Annual Invention Report is due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the

			expiration date of the contract.
13	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
14	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices discussing data obtained under this contract are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
15	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours of an activity or incident.
16	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 90 days of contract award.
17	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
18	Quality Management System Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
19	Notification of Critical Programmatic Concerns, Risks, or Potential Risks (i.e. Incident Report)	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall alert the CO and COR within one (1) business day after notification of an incident, provide updates within two (2) business days of additional developments, submit corrective action plans as required in Section F.3.3 above and provide an incident report

			within 45 days of the incident.
20	QA Audit	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall submit a report to the CO and COR detailing the finding(s) and corrective action(s) within 60 days of the audit or site visit.
21	BARDA Audit	CO: (1) electronic copy COR: (1) electronic copy	If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding(s) and corrective action(s) within 15 business days of the audit.
22	Go/No-Go In-Process Review (IPR)	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall provide presentation materials to CO and COR 10 business days prior to the IPR. Submit written justification of progress towards satisfying Go/No- Go criteria. CO/COR will provide a written response within 10 days.
23	Contractor's Data Sharing Plan	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall submit plan within 90 days of the effective date of the contract.

F.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEB 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/browse/index/far.

- FAR 52.242-15, Stop Work Order (August 1989) – applicable to FFP CLINs
- FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (April 1984) – applicable to CPFF CLIN

SECTION G – CONTRACT ADMINISTRATION

G.1. CONTRACTING OFFICER (CO)

The Contracting Officer is the only individual who can legally commit and bind the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

The CO is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of objectives; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; (6) sign written licensing agreements; or (7) otherwise change any terms and conditions of this contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

The Contracting Officer (CO) is:

Jill Johnson (jill.johnson@hhs.gov)

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

As delegated by the CO, the Contracting Officer's Representative (COR) is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer's Representative (COR) is:

Ramya Natarajan, PhD (ramya.natarajan@hhs.gov)

The Alternate Contracting Officer's Representative (Alt-COR) is: Xi Lu, PhD (xi.lu@hhs.gov)

G.3. CONTRACTOR'S POINTS OF CONTACT

The Contractor shall provide primary and secondary points of contact that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency, as follows:

Primary Point of Contact:

[*]

[*]
cell: [*]
email: [*]

Secondary Point of Contact:

[*]

[*]

cell: [*]
email: [*]

G.4. KEY PERSONNEL, HHSAR 352.237-75 (DEC 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
[*]	[*]
[*]	[*]

G.5. Electronic Invoicing and Payment Requirements – Invoice Processing Platform (IPP)

- All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).
- Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.
- The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
    - Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via

email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

- The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

- If your company is already registered to use IPP, you will not be required to re-register.
- If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

G.5.1. Additional Administration for Strategic Preparedness and Response (ASPR) requirements:

- The contractor shall submit monthly invoices under this contract unless otherwise agreed upon by all parties. For indefinite delivery and blanket purchase agreement vehicles, separate invoices must be submitted for each order.
- Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.
- Invoices must include the Dun & Bradstreet Number (DUNS) of the Contractor.
- Invoices that include time and materials or labor hours CLINs must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and
  (2) substantiate material costs incurred (when applicable).
- Invoices that include cost-reimbursement CLINs must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, scope of work, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

G.6. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor under the CPFF CLINs for the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in SECTION I – CONTRACT CLAUSES, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a. All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b. All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c. All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d. Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

   i. Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

   ii. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

   iii. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

   iv. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.7. NEGOTIATED INDIRECT COST RATES (Applied to CPFF CLINs)

a. The following provisional billing rates are incorporated into the contract and will be utilized for billing purposes during the Base Period pending the establishment of final indirect cost rates for each fiscal year or until revised by the CO in accordance with the provisions of FAR 42.705-1.

Rate Type	Rate Ceiling	Allocation Base
Fringe Benefits	[*] %	Total Salaries
General and Administrative	[*] %	Total Direct Costs Plus Applied Fringe

b. Notwithstanding the provisions of FAR 42.704, ceilings are hereby established on indirect costs reimbursable under this contract. Therefore, the Government will not be obligated to pay any additional amounts if the final indirect cost rates developed by the cognizant audit

activity based on actual allowable costs exceed the ceiling rates set forth above. In the event the final indirect cost rates are less than the above-established ceiling rates, the negotiated final rates shall be reduced to conform to the lower rates

c. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rate proposal to the contracting officer and the cognizant auditor within the six- month period following the end of each of its fiscal years during the period of contract performance. The contracting officer may grant, in writing, reasonable extensions, for exceptional circumstances only, when requested in writing by the contractor. The Government shall not be obligated to (1) pay any additional amount should the final indirect cost rates exceed the established ceiling rates, and (2) in the event the final rates are less than the established ceiling rates, the negotiated rates will be reduced to conform with the lower rates.

G.8. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor for the CPFF CLINs to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under SECTION J entitled, “Financial Report of Individual Project/Contract.”

G.9. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS
Contracting Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at: https://archive.org/details/contractorsguide00unit.
Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated in this contract in paragraph 1 above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary

reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is attached to this contract (see SECTION J – LIST OF ATTACHMENTS). Title will vest in the Government for equipment purchased as a direct cost under the CPFF CLINs.

G.10. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

G.11. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. *Purpose:* In accordance with FAR Subpart 42.15, the Contractor's performance will be periodically evaluated by the government in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

b. *Performance Evaluation Period*: The Contractor's performance will be evaluated at least annually.

c. *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

d. *Performance Evaluation Factors*: The Contractor's performance will be evaluated in accordance with FAR Subpart 42.15 and Attachment #5, Contract Performance Evaluation Report.

e. Contractor *Review*: A copy of the evaluation will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.

f. *Resolving Disagreements between the Government and the* Contractor: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

g. *Release of* Contractor *Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.

h. *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

i. *Retention Period*: The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1. PROTECTION OF HUMAN SUBJECTS

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

d. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Human Subject Assurances.

H.2. CLINICAL RESEARCH

These Clinical Terms apply to all grants and contracts that involve clinical research.

The Government shall have rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

H.2.1. Safety and Monitoring Issues

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award or upon regulatory acceptance and then with Annual Progress Reports, the Contractor shall submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

a. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
b. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
c. Termination or temporary suspension of patient accrual.
d. Termination or temporary suspension of the protocol.
e. Any change in IRB approval.
f. Any other problems or issues that could affect the participants in the studies.

H.2.2. Data and Safety Monitoring Requirements

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under the CPFF CLINs of this contract. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

a. Independent Safety Monitor – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

b. Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.

c. Data and Safety Monitoring Board – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) for Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

b. IRB or IEC approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria;

c. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name;

d. IRB or IEC approved informed consent document, identified by version number, date, or both and date it is valid;

e. Plans for the management of side effects;

f. Procedures for assessing and reporting adverse events;

g. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory;

h. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within ten (10) business days of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written Contracting Officer Authorization (COA) letter may be provided to the Contractor. This COA provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

H.2.4. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA Contracting Officer's representative (COR) as follows:

a. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the BARDA program officer or the Contracting Officer's Representative within 24 hours of FDA notification.

b. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.

c. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.

d. *Expedited safety reports* – shall be sent to the BARDA COR concurrently with the report to FDA.

e. Other adverse events documented during the course of the trial shall be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

Safety reporting for research not performed under an IND or IDE.

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

H.3. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

H.4. HHSAR 352.270-12 NEEDLE EXCHANGE (DEC 2015)

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.5. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

H.6. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.7. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (DEC 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under **7 U.S.C. 2133** and **9 CFR 2.1 2.11**, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see **7 U.S.C. 2131** et seq. and **9 CFR subchapter A, Parts 1-4**). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

H.8. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

H.9. HHSAR 352.211-3 PAPERWORK REDUCTION ACT (DEC 2015)

a. This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

b. The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

H.10. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

H.11. 352.239-74 ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (DEC 2015)

a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and- standards/communications-and-it/about-the-section-508-standards.

b. The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

c. The Section 508 accessibility standards applicable to this contract are: E205 Electronic Content Standards. Note: Items provided incidental to contract administration are not subject to this section.

d. In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer

may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

e. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

H.12. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping

provisions in other Federal, State or local laws.

H.13. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR CONFLICTS OF INTERESTS

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/current/title-45/part-94

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

    1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
    2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA funded research.

d. Require that each Investigator who is planning to participate in the BARDA funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for BARDA funded research. Require that each Investigator who is participating in the BARDA funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.14. PUBLICATION AND PUBLICITY

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall provide and the Contracting Officer shall approve an advance copy of any such press release not less than five (5) business days prior to the issuance of any potential press release.

The Contractor shall acknowledge the support of the Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with federal funds from the Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. Insert Contract Number ".

H.15. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The website to file a complaint on-line is: https://oig.hhs.gov/fraud/report-fraud/ and the mailing address is:

US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

H.16. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and Pub. L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.17. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance, all data generated, all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Contractor commitments and responses. The Contractor shall provide the Government with an electronic copy of all correspondence with the FDA within five (5) business days of submission to or receipt from FDA. The Government shall acquire rights to all data funded under any contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.18. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under the CPFF CLINs of this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other such data determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.19. DISSEMINATION OF INFORMATION

Except for necessary releases to subcontractors and advisors and in connection with regulatory reporting requirements, no information related to data obtained under the CPFF CLINs of this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.20. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers,

educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at: http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx

H.21. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (https://www.ecfr.gov/current/title-42/part-73) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/

H.22. SHARING RESEARCH DATA

The Contractor's data sharing plan, due within 90 days of the effective date of the contract, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA- funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.23. DISCLOSURE OF FINANCIAL PERFORMANCE AND TRANSFER OF TECHNOLOGY

This clause shall remain in effect during the term of the Contract.

a. Contractor Financial Performance

The Contractor shall provide quarterly a summary or collection of financial statements, such as balance sheets, income statements, and cash flow statements. These may include SEC filings or other documents that highlight Contractor revenues and expenditures to be agreed upon with consultation from the Contracting Officer and COR. Additionally, the company must notify the Contracting Officer of financial issues leading to potential liquidation of assets as soon as feasible after notifying the SEC.

b. Post-award Transfer of Ownership of Technology

The Contractor shall provide notice to the Contracting Officer and COR upon entering into any new term sheet, between the Contractor and an external party, that outlines the transfer of ownership, or operational, corporate, or economic control of technology or establishment of a licensing agreement of any technology funded under this Contract from the Contractor to another institution. This clause excludes subcontracts.

H.24. HHSAR 352.270-13 CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (DEC 2015)

a. The Contractor shall not use any funds obligated under this contract for any abortion.

b. The Contractor shall not use any funds obligated under this contract for the following:

(1) The creation of a human embryo or embryos for research purposes; or

(2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR Part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

c. The term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR Part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

d. The Contractor shall not use any Federal funds for the cloning of human beings.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) FFP SUPPLIES CLAUSES

Full text of the FAR clauses may be accessed electronically at: https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jun 2020	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Jun 2020	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Jun 2020	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Nov 2021	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Nov 2021	Display of Hotline Poster(s)
FAR	52.203-17	Jun 2020	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.204-21	Nov 2021	Basic Safeguarding of Covered Contractor Information Systems
FAR	52.204-23	Nov 2021	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-25	Nov 2021	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.209-6	Nov 2021	Protecting the Government's Interests When Subcontracting With Offerors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Nov 2021	Market Research
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.215-2	Jun 2020	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data
FAR	52.215-11	Jun 2020	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-12	Jun 2020	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Jun 2020	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Nov 2021	Integrity of Unit Prices
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions

FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Nov 2021	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
FAR	52.215-23	Jun 2020	Limitations on Pass-Through Charges
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-28	Sep 2021	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Jun 2020	Equal Opportunity for Veterans
FAR	52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun 2020	Employment Reports on Veterans
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Nov 2021	Combating Trafficking in Persons
FAR	52.222-54	May 2022	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Jun 2020	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.224-1	Apr 1984	Privacy Act Notification
FAR	52.224-2	Apr 1984	Privacy Act
FAR	52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	June 2020	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General, Alternate II
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-8	Feb 2002	Discounts for Prompt Payment
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	May 2014	Interest
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Nov 2021	Providing Accelerated Payments to Small Business SubOfferors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-2	Apr 1991	Production Progress Reports
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price Alternate V (Apr 1984).
FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-6	Jan 2022	Subcontracts for Commercial Products and Commercial Services
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services

FAR	52.247-34	Nov 1991	F.o.b Destination
FAR	52.247-67	Feb 2006	Submission of Transportation Documents for Audit
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.253-1	Jan 1991	Computer Generated Forms

I.2. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CPFF RESEARCH AND DEVELOPMENT CLAUSES

Full text of the FAR clauses may be accessed electronically at: https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jun 2020	Definitions
FAR	52.203-3	Apr 1984	Gratuities
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FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Nov 2021	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Nov 2021	Display of Hotline Poster(s)
FAR	52.203-17	Jun 2020	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
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FAR	52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.204-21	Nov 2021	Basic Safeguarding of Covered Contractor Information Systems
FAR	52.204-23	Nov 2021	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
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FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
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FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes

FAR	52.215-21	Nov 2021	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
FAR	52.215-23	Jun 2020	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-28	Sep 2021	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept 2016	Equal Opportunity
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FAR	52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun 2020	Employment Reports on Veterans
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Nov 2021	Combating Trafficking in Persons
FAR	52.222-54	May 2022	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
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FAR	52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
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FAR	52.227-1	June 2020	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General, Alternate II
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Nov 2021	Providing Accelerated Payments to Small Business SubOfferors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-2	Apr 1991	Production Progress Reports
FAR	52.242-3	Sep 2021	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984).
FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
FAR	52.244-5	Dec 1996	Competition in Subcontracting

FAR	52.244-6	Jan 2022	Subcontracts for Commercial Products and Commercial Services
FAR	52.245-1	Sep 2021	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.247-67	Feb 2006	Submission of Transportation Documents for Audit
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

I.1. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses may be accessed electronically at https://www.acquisition.gov/hhsar/part-352- solicitation-provisions-and-contract-clauses

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-2	Dec 2015	Conference Sponsorship Requests and Conference Materials Disclaimer
HHSAR	352.215-70	Dec 2015	Late Proposals and Revisions
HHSAR	352.216-70	Dec 2015	Additional Cost Principles
HHSAR	352.222-70	Dec 2015	Offeror Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2015	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.270-6	Dec 2015	Restriction on use of Human Subjects
HHSAR	352.270-9	Dec 2015	Non-Discrimination for Conscience

I.2. ADDITIONAL CONTRACT CLAUSES

I.4.1. Additional HHS Acquisition Regulation (HHSAR) Clauses – In Full Text HHSAR 352.231-70 Salary

Rate Limitation (DEC 2015)

f. The Offeror shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated

g. For purposes of the salary rate limitation, the terms ‘‘direct salary,’’ ‘‘salary,’’ and ‘‘institutional base salary’’ have the same meaning and are collectively referred to as ‘‘direct salary’’ in this clause. An individual’s direct salary is the annual compensation that the Offeror pays for an individual’s direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Offeror. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs).

The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with federal funds.

d. The salary rate limitation also applies to individuals under subcontracts.

e. If this is a multiple-year contract or order, it may be subject to unilateral modification by the CO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

f. See the salaries and wages pay tables on the U.S. Office of Personnel Management website for federal Executive Schedule salary levels.

HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2022)

a. Definitions. As used in this clause—Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

b. Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

c. The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

d. If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

I.4.2. Additional FAR (48 CFR Chapter 1) Clauses – In Full Text

52.217-7 Option for Increased Quantity -- Separately Priced Line Item (MAR 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The CO may exercise the option by written notice to the Contractor. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

PART III – ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated 08/25/2022, 12 pages
2. Invoice Instructions for Cost Reimbursement Contracts
3. Invoice Instructions for Fixed Price Contracts
4. Sample Invoice Form
5. Protection of Human Subjects - https://www.hhs.gov/ohrp/register-irbs-and-obtain- fwas/forms/index.html
6. BARDA Security Requirements
7. Financial Report of Individual Project/Contract
8. Report of Government Owned, Contractor Held Property

Attachment 1 - Statement of Work

SMALLPOX ANTIVIRAL
Date 08/25/2022

1. PREAMBLE

Independently and not as an agent of the USG, the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment, and facilities (except Government property) to develop and deliver FDA-approved smallpox therapeutic with an alternative mechanism of action to address the potential for the development of resistance to the current stockpile drug.

In accordance with FAR 52.243-2, Changes-Cost Reimbursement (Alt. V), the Government reserves the right to modify the milestones, progress, schedule, budget, or to add or delete deliverables, process or schedules if the need arises. Because of the nature of the research and development (R&D) elements of the contract and the complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made.

1.0 Overall Objectives and Scope

The overall objective of this contract is to procure a second approved smallpox antiviral for delivery to the Strategic National Stockpile (ASPR/SNS) to achieve the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) smallpox preparedness requirement of having two readily available smallpox antivirals with distinct mechanisms of action. The scope of work for this contract includes the manufacture and delivery of up to 1.7 Million Treatment Courses (TCs) of the smallpox antiviral TEMBEXA®, with an approximate 90/10 split of oral tablets/oral suspension to the SNS site(s) and the associated activities to support these deliveries, and post approval Research and Development (R&D) activities: Post Marketing Commitment (PMC) non-clinical activities; Post Marketing Requirement (PMR) clinical activities; oral suspension formulation post marketing manufacturing scale-up activities; shelf-life extension support clinical activities and all associated regulatory, quality assurance, management, and administrative activities. The Procurement and R&D efforts for the TEMBEXA program will progress in specific stages that cover Base Periods and Option Periods as specified in this contract. The scope of work has been broken into the following seven (7) CLINs which are discrete work segments:

1. Base CLIN 1 Post Marketing Commitments, Suspension Manufacturing Scale- up and Other Stability Extension Support
2. Base CLIN 2 Delivery of FDP to the SNS
3. Option CLIN 3 Conduct of Ph 4 PMR Field Study
4. Option CLIN 4 Delivery of FDP to the SNS
5. Option CLIN 5 Delivery of FDP to the SNS
6. Option CLIN 6 Delivery of FDP to the SNS
7. Option CLIN 7 Delivery of FDP to the SNS

2. Applicable Documents

Approved UNITED STATES PRESCRIBING INFORMATION (USPI) FOR TEMBEXA

3. Statement of Work

Provide a 2nd FDA approved antiviral for the treatment of smallpox, including delivery of product to the SNS, post-approval research and development (R&D), scale-up of suspension formulation, post marketing requirement (PMR), post-marketing commitment (PMC) as set forth below.

3.1 CLIN 1 POST MARKETING COMMITMENTS, SUSPENSION MANUFACTURING SCALE-UP AND OTHER STABILITY EXTENSION SUPPORT

Complete all efforts required to fulfill the PMR protocol and PMC study established by the FDA. This includes development of a clinical Phase 4 Field Study protocol in the event of a smallpox outbreak as well as a cell culture study to characterize TEMBEXA antiviral activity against specific mutant viruses. [*]. Additionally, it includes Program Management, post-licensure Regulatory and Safety requirements and Quality Assurance (QA).

3.1.1 Program Management

As outlined below and in the contract deliverables the Contractor shall:

3.1.1.1 Program Management Deliverables

3.1.1.1.1 Provide and maintain a list of individuals to serve as primary and secondary points of contact who will be notified in case of a public health emergency.

3.1.1.1.2 Provide Key Milestones as part of the Integrated Master Project Plan, outlining key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due within 90 days after contract award. Updates shall be due as requested by the Contract Officer (CO) or Contracting Officer Representative (COR).

3.1.1.1.3 Provide an Integrated Master Schedule (IMS), which will include key milestones, as part of the Integrated Master Project Plan. Within 30 calendar days of the effective date of the contract submit a first draft of an updated IMS in a format agreed upon by BARDA to the CO and COR for review and comment.

3.1.1.1.4 Provide a Work Breakdown Structure (WBS) as part of the Integrated Master Project Plan. Utilize a WBS template agreed upon by BARDA for reporting on the contract. BARDA may require WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

3.1.1.1.5 Provide a Risk Management Plan/Matrix: Develop and maintain a risk management plan/matrix that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate

remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. This report shall be due within 90 days of contract award. Updates shall be due as requested by the CO or COR.

3.1.1.1.1 Provide a Security Plan associated with all aspects of manufacture of product, process, storage and inventory. The Security Plan includes all sites within the supply chain, including proposed shipping carriers. For those sites/carriers that are not defined at the time of award or are added during the period of performance, individualized Security Plans shall be provided to the USG prior to inclusion of sites/carriers into the supply chain. This report shall be due within 90 days of contract award. Updates shall be due as requested by the CO or COR.

3.1.1.1.6.1 Provide access to BARDA's Program Protection Office to review and approve Security Plans and conduct audits / site visits as requested to ensure a reliable product is delivered to the USG.

3.1.1.1.1 Provide copies of Manufacturing Plan as approved in NDA(s) upon request of the CO or COR. Updates shall be due as requested by the CO or COR.

3.1.1.1.2 Provide a Manufacturing/Delivery Schedule to the ASPR/SNS within 30 days of agreement on SNS delivery location

3.1.1.1.3 Provide a Quality Manual describing the Quality Management System (QMS) within 90 Days of contract award. Updates shall be due as requested by the CO or COR.

3.1.1.1.4 Complete a Quality Agreement between BARDA, SNS and Chimerix within 30 Days of contract award.

3.1.1.2 **Progress Reports**

3.1.1.2.1 Deliver a Monthly Project Status Report on or before the 15th calendar day following the last day of each reporting period. A Monthly Progress Report will not be required in the same month Annual Progress Reports or a Final Report are due. This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period.

3.1.1.2.2 Deliver an Annual Progress Report on or before the 30th calendar day following the last day of each reporting period. An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due. This report shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period.

3.1.1.2.3 Submit a Draft Final Report and Deliver a Final Report. These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report shall be due forty-five (45) calendar days prior to the expiration date of the contract and the Final Report is due on or before the expiration date of the contract.

3.1.1.1.4 Submit a Quarterly Financial Report on or before the 30th calendar day following the last day of each reporting period.

3.1.1.3 **Meetings/Site Visits**

3.1.1.3.1 Plan and conduct a kick-off meeting within 30 days of contract award. The purpose of the kickoff meeting will be to orient the Contractor to HHS/BARDA and review contract requirements. The goals of the kick-off meeting are as follows:

- Jointly assess areas such as planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks
- Review and approve the project milestones
- Review and approve the Integrated Master Schedule and set a baseline
- Review and approve the Risk Management Matrix
- Review and approve the Quality Agreement
- Present and review the Delivery Schedule to the ASPR/SNS for the Base CLIN and all Optional CLINs
- Draft minutes (for approval at the next meeting) will be due no later than seven (7) business days following the kick-off Meeting.

3.1.1.3.2 Participate in expected bi-weekly or monthly status update meetings/teleconferences to coordinate and oversee the contract effort. Such meetings may include, but are not limited to updates on PMRs, PMCs, scale-up manufacturing development, clinical pharmacology studies, and regulatory issues; meetings with subcontractors/consultants and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor. The schedule for these meetings will be established by the CO and COR.

- Meeting agendas are due no later than two business days before each meeting.
- Meeting minutes are due no later than seven (7) business days following each meeting.

3.1.1.3.3 Participate in In-Process Review (IPR) as requested by CO and COR (up to 1 per year). Contractor shall provide presentation materials to CO and COR 10 business days prior to the IPR. Submit written justification of progress towards satisfying Go/No-Go criteria. CO/COR will provide a written response within 10 days.

3.1.1.4 **Audits**

3.1.1.4.1 Notify the CO and COR within one (1) business day of FDA presence on site to conduct site visits/audits. Provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) for content that is pertinent to the contract. Provide the COR and CO copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plan execution, and a copy of all final

responses to the FDA. Provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. When appropriate, make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

3.1.1.4.2 Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

3.1.1.4.3 Qualify vendors involved in cGMP production and GCP clinical studies using Contractor's existing Quality Management System. Perform initial assessment of all subcontractors in accordance with existing SOPs. Conduct on-site audits as needed where suitable standards of GxP are employed and work is initiated, including dissemination of relative audit report detailing any observations to the vendor. Conduct on-site audits at strategic times once a vendor's work has been initiated as part of the overall management of the project.

3.1.1.4.3.1 Within 30 days of receipt of a final audit report, procure a written response from vendor that describes corrective actions.

3.1.1.4.3.2 Notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.

3.1.1.4.3.3 Notify the COR and CO within five (5) business days of report completion.

3.1.1.4.4 Accommodate periodic or reasonable *ad hoc* site visits from BARDA during normal business hours by the Government where two (2) business days advance notice has been given. If the Government, the Contractor, or other parties identifies any issues during an audit, capture the issues, identify potential solutions, and provide a report to the Government.

3.1.1.4.4.1 If issues are identified during the audit, submit a report to the CO and COR detailing the finding and corrective action(s) within 15 business days of the audit.

3.1.1.4.4.2 COR and CO will review the report and provide a response within ten (10) business days.

3.1.1.4.4.3 Once corrective action is completed, provide a final report to the CO and COR within a time frame negotiated with the COR in writing after review of the issues report.

3.1.1.5 **Other Communication Deliverables**

3.1.1.5.1 Technology packages developed under the contract including complete protocols must be submitted within 10 business days of request by the COR. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data.

3.1.1.5.2 The Contractor shall submit to the COR Draft Protocols and associated study/experiment/test plans 30 days prior to study initiation prior to submission to

regulatory agencies (IACUC, FDA, etc.). The Contractor shall submit to the COR Final Protocols 10 business days prior to the execution of the study or within 10 business days of request by the COR. Approval must be provided in writing by the COR prior to the execution of the study. Draft Reports are due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to the FDA. Final Reports are due 30 calendar days after receiving comments on the Draft Report. Final FDA submissions shall be provided to BARDA concurrently or no later than one (1) business day after submission to the FDA.

3.1.1.5.3 Submit an Annual Invention Report on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract.

3.1.1.5.4 Submit any manuscript or scientific meeting abstract containing data generated under this contract to COR for review prior to submission. Reports shall be due within 30 calendar days for manuscripts and 15 calendar days for abstracts.

3.1.1.5.5 In any press release where work performed pursuant to this SOW is discussed or presented, Contractor will, in all material respects, accurately represent the work conducted. Ensure the CO or COR has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

3.1.1.5.6 Report to the government any activity; or incident that is in violation of the agreed upon Security Plan; or indicates the loss or theft of government products. Communication shall be due within 24 hours after occurrence of an activity or incident.

3.1.1.5.7 Provide an Incident Report for any major developments or deviations that significantly impact the Contractor's ability to successfully meet objectives, deliverables or schedule (e.g., significant manufacturing deviations or loss, BSL-4 laboratory incidents, etc.).

3.1.1.5.8 Provide raw data and/or specific analysis of data generated with USG funds within 20 business days of request from CO or COR and amend reports if required and adjudicate all comments.

3.1.1.5.9 Submit a Deviation Report upon request of the COR when any needed changes to IMS activities as baselined at the kick-off meeting are required. This report shall request a change in the agreed-upon IMS and timelines. This report shall include: (i) discussion of the justification/rationale for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost- benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

3.1.1.5.10 Submit Draft report within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Final report due 30 calendar days after receiving comments on the Draft report for Clinical and Non-Clinical Studies. Final

FDA submissions shall be provided to BARDA concurrently or no later than one (1) business day after submission to the FDA.

3.1.1.6 **FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions**

3.1.1.6.1 Inform BARDA of all communications with the FDA for the orthopox indications for this specific product, provide all communications and submissions related to the product, and provide previous correspondences with FDA related to the development of the therapeutic within five (5) business days of submission to or receipt from FDA.

3.1.1.6.2 Maintain and update, as required by the FDA, all required regulatory documentation (including but not limited to; investigator brochure, annual reports, PADERs DSURs), that will be used to support continued licensure.

3.1.1.6.3 Provide, within five (5) business days of any informal meeting with the FDA or other regulatory agency, initial draft minutes to BARDA. Forward the final minutes when available and if applicable.

3.1.1.6.4 Provide BARDA any documents to be submitted to the FDA or other regulatory agency within five (5) business days prior to submission, without impacting meeting FDA deadlines.

3.1.1.6.5 Submit Standard Operating Procedures (SOPs) related to the Product upon reasonable request from COR.

3.1.1.6.6 Generate all necessary documentation for the [*]. Provide Regulatory support in accordance with 3.1.1.6.

3.1.1.6.7 Provide expertise and advise on [*] regulatory filings. Provide authoring, review, and guidance during FDA submissions. Provide publishing work for [*]

3.1.2 **Post Marketing Requirements and Commitments**

Comply, in all material respects, with Post-Marketing Requirements/Commitments as specified by the FDA. Work scope may be revisited once final FDA guidance on PMR has been provided.

3.1.2.1 Collaborate with [*] and other stakeholders to finalize and submit the PMR clinical Ph 4 Field Study Protocol to the FDA to evaluate TEMBEXA [*]when used for the treatment of human smallpox disease due to VARV infection. Support all work to implement required state of readiness for the field study.

3.1.2.2 Generate all necessary documentation for the set-up and oversight of pharmacovigilance safety reporting for TEMBEXA.

3.1.2.2.1 Support PVG tracking and database updates for studies using TEMBEXA.

3.1.2.2.2 Track and prepare all required reporting and assessments for PVG. Provide to BARDA and FDA as required.

3.1.2.3 Conduct a study to complete a post-marketing commitment to characterize brincidofovir antiviral activity against recombinant vaccinia viruses encoding specific amino acid substitutions.

3.1.2.3.1 Provide final protocols and reports that will be shared with BARDA and the FDA.

3.1.2.3.2 Provide Analyzed Data to BARDA at Status Update Meeting

3.1.2.3.3 Provide Final Reports in accordance with 3.1.1.5.10

3.1.2.4 Store additional samples from past studies until PMC work is complete.

3.1.3 **[*]**

3.1.3.1 Conduct [*].

3.1.3.2 Provide the necessary biostatistical data and data management services [*].

3.1.3.3 Author the Clinical Study Report (CSR) [*].

3.1.3.4 Submit all required regulatory documentation (CBE 30) [*].

3.1.4 **Clinical Pharmacology**

3.1.4.1 Develop and validate assay [*].

3.1.4.2 Provide analytical testing (including pharmacokinetics) of drug in plasma samples [*]

3.1.5 **[*]**

3.1.5.1 [*]

3.1.5.2 [*].

3.1.5.3 Complete an [*]

3.1.5.4 Upon completion [*].

3.1.6 **[*]**

3.1.6.1 [*].

3.1.6.2 Provide annual stability data for shelf-life extension to BARDA.

3.1.6.3 Submit annual stability data for shelf-life extension to FDA as required.

3.2 CLIN 2 DELIVERY OF FDP TO THE SNS

Under CLIN 2 provide initial shipment of product 319,000 treatment courses of a therapeutic against smallpox, in accordance with all federal, state and local regulations, as well as international regulations if applicable. As outlined below and in the contract deliverables the Contractor shall:

3.2.1 **Manufacture and deliver smallpox antiviral Final Drug Product (FDP) treatment courses of 100 mg tablets.**

3.2.1.1 [*].

3.2.1.2 [*].

3.2.2 **Manufacture and deliver smallpox antiviral FDP treatment courses of 10 mg/mL oral suspension.**

3.2.2.1 [*].

3.2.2.2 [*].

3.3 CLIN 3 CONDUCT OF PH 4 PMR FIELD STUDY

Under CLIN 3 support all FDA post marketing requirements in the conduct of a Ph 4 Field Study as outlined in 3.1.2.1. Work scope may be revisited once final FDA guidance on PMR has been provided.

As outlined below and in the contract deliverables the Contractor shall:

3.3.1 **Program Management**

3.3.1.1 Manage program scope as described CLIN 1.

3.3.1 **Ph 4 PMR Field Active Study (in the event of an outbreak)**

3.3.2.1 Support the NIH in the conduct the PMR clinical Ph 4 Field Study to evaluate [*].

3.3.2.2 Collaborate with NIH to generate all necessary regulatory documentation for the completion for the TEMBEXA PMR, conduct of a Ph4 Field Study in accordance with 3.1.1.6.

3.3.2.3 Where and when possible, set up and calibrate equipment and train staff at sites enrolled in the Ph4 Field Study to collect and process PBMC samples

3.3.2.4 Perform analytical testing [*]

3.3.2.5 Complete [*]

3.4 CLIN 4 DELIVERY OF FDP TO THE SNS

Under CLIN 4 in order to augment the existing inventory of smallpox therapeutic MCMs stored in the SNS and/or replace expiring product, send additional shipment of [*] treatment courses of a therapeutic against smallpox. As outlined below and in the contract deliverables the Contractor shall:

3.4.1 **Manufacture and deliver smallpox antiviral Final Drug Product (FDP) treatment courses of 100 mg tablets.**

3.4.1.1 [*].

3.4.1.2 [*].

3.4.2 **Manufacture and deliver smallpox antiviral FDP treatment courses of 10 mg/mL oral suspension.**

3.4.2.1 [*].

3.4.2.2 [*].

3.5 CLIN 5 DELIVERY OF FDP TO THE SNS

Under CLIN 5 in order to augment the existing inventory of smallpox therapeutic MCMs stored in the SNS and/or replace expiring product, send additional shipment of [*] treatment courses of a therapeutic against smallpox. As outlined below and in the contract deliverables the Contractor shall:

3.5.1 **Manufacture and deliver smallpox antiviral Final Drug Product (FDP) treatment courses of 100 mg tablets.**

3.5.1.1 [*].

3.5.1.2 [*].

3.5.2 **Manufacture and deliver smallpox antiviral FDP treatment courses of 10 mg/mL oral suspension.**

3.5.2.1 [*].

3.5.2.2 [*].

3.6 CLIN 6 DELIVERY OF FDP TO THE SNS

Under CLIN 6 in order to augment the existing inventory of smallpox therapeutic MCMs stored in the SNS and/or replace expiring product, send additional shipment of [*] treatment courses of a therapeutic against smallpox. As outlined below and in the contract deliverables the Contractor shall:

3.6.1 **Manufacture and deliver smallpox antiviral Final Drug Product (FDP) treatment courses of 100 mg tablets.**

3.6.1.1 [*].

3.6.1.2 [*].

3.6.2 **Manufacture and deliver smallpox antiviral FDP treatment courses of 10 mg/mL oral suspension.**

3.6.2.1 [*].

3.6.2.2 [*].

3.7 CLIN 7 DELIVERY OF FDP TO THE SNS

Under CLIN 7 in order to augment the existing inventory of smallpox therapeutic MCMs stored in the SNS and/or replace expiring product, send additional shipment of [*] treatment courses of a therapeutic against smallpox. As outlined below and in the contract deliverables the Contractor shall:

3.7.1 **Manufacture and deliver smallpox antiviral Final Drug Product (FDP) treatment courses of 100 mg tablets.**

3.7.1.1 [*].

3.7.1.2 [*].

3.7.2 **Manufacture and deliver smallpox antiviral FDP treatment courses of 10 mg/mL oral suspension.**

3.7.2.1 [*].

3.7.2.2 [*].

ATTACHMENT #2

INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after

settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and UEI:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), Unique Entity Identifier (UEI). The UEI must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and UEI).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed- fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three- way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice

Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- Item number for the specific piece of equipment listed in the Property Schedule, and

- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List Subcontractors by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. Subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

ATTACHMENT #3

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

General: The Contractor shall submit vouchers or invoices as prescribed herein.

Format: Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency: Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice: The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

The Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor’s name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form
HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor.
Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

ATTACHMENT #4
SAMPLE INVOICE/PAYMENT REQUEST

(a) Designated Billing Office Name and Address: DHHS/OS/ASPR/BARDA/CMA Attn: Jill Johnson, Contracting Officer US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE Division of Contract Management & Acquisitions O'NEILL HOUSE OFFICE BUILDING Washington DC 20515 (b) Contractor's Name, Address, Point of Contact, VIN, and UEI: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:** **UEI:**	(c) Invoice/Financing Request No.: (d) Date Invoice Prepared: (e) Contract No. and Order No. (if applicable): (f) Effective Date: (g) Total Estimated Cost of Contract/Order: (h) Total Fixed-Fee (if applicable): (i) Two-Way Match: Three-Way Match: (j) Office of Acquisitions: (k) Central Point of Distribution:

(l) This invoice/financing request represents reimbursable costs for the period from __ to

TABLE 1 of 2

Expenditure Category* A	Cumulative Percentage of Effort/Hrs.		Amount Billed		Cost at Completion F	Contract Amount G	Variance H
	Negotiated B	Actual C	(m) Current D	(n) Cumulative E			
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							

(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____

(Name of Official) (Title)

* Attach details as specified in the contract

TABLE 2 of 2

CLIN	**Requisition Number**	**Mod #**	**Total Funds Obligated**	**Cumulative Spend to Date**	**Remaining Funds**	**Spend Current Invoice**
CLIN XXXX	OS#XXXXXX	#	$	$	$	$

OMB No. 0990-0263
Approved for use through June 30, 2024

Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule unless the activities are exempt from or approved in accordance with the Common Rule. The "pre-2018 Common Rule (or pre-2018 Requirements)" was originally promulgated in 1991 and amended on June 23, 2005 (70 FR 36325). The "2018 Common Rule (or 2018 Requirements)" was originally published on January 19, 2017 (82 FR 7149) and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497). The categories of exempt research are provided in Section 101(b) of the pre-2018 Common Rule and Section 104(d) of the 2018 Common Rule.

The pre-2018 Common Rule requires institutions to certify that each application or proposal for research has been reviewed and approved by an Institutional Review Board (IRB) (Section 103(f)). The 2018 Common Rule requires institutions to certify that each proposed research study has been reviewed and approved by an IRB (Section 103(d)). Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal, or proposed research study, unless otherwise advised by the Department or Agency.

<table>
<tr><td>1. Request Type [ ]

ORIGINAL
[CONTINUATION [ ]
EXEMPTION</td><td>2. Type of Mechanism [ ]

GRANT
[ ] CONTRACT
[ ] FELLOWSHIP
[ ] COOPERATIVE AGREEMENT
[ ] OTHER:</td><td>3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.</td></tr>
<tr><td colspan="2">4. Title of Application or Activity</td><td>5. Name of Principal Investigator, Program Director, Fellow, or Other</td></tr>
</table>

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with the Department of Health and Human Services, covers this activity:

Assurance Identification No. ____, the expiration date __ IRB Registration No. __

[ ] This Assurance, on file with *(agency/dept)* __, covers this activity.

Assurance No. __, the expiration date __IRB Registration/Identification No. ____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under the pre-2018 Common Rule, Section 101(b), paragraph __.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under the 2018 Common Rule, Section 104(d), paragraph __

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.

by:
[ ] Full IRB Review on (date of IRB meeting) ____ or [ ] Expedited Review on (date) __

[ ] If less than one year approval, provide expiration date __

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct	10. Name and Address of Institution

and that, as required, future reviews will be performed until study closure and certification will be provided.	
11. Phone No. *(with area code)* 12. Email:	
13. Name of Official	14. Title
15. Signature	16. Date

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ATTACHMENT #6

BARDA SECURITY REQUIREMENTS

The following table outlines the minimum security requirements for any partner facility receiving a BARDA contract under which the USG purchases products or technologies.

1. Security Administration	
Security Program	The partner facility shall have a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. The proposal submitted shall include a security plan which establishes security practices and procedures that demonstrate how the Offeror will meet and adhere to the security requirements outlined below by time of contract award. The Offeror shall also ensure that other entities (subcontractors, consultants, etc.) performing work on behalf of the Offeror establishes and manages a security program that complies with BARDA security requirements.
2. Facility Security Plan	
As part of the partner facility's overall security program, they shall submit a written security plan with their proposal to BARDA for review and approval by the BARDA PPO. Performance of work under the BARDA contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	Organization and responsibilities; security risk assessment for site; threat levels identification matrix; security procedures during elevated threats; liaison with law enforcement; security education and training
Personnel Security Policies and Procedures	Candidate recruitment process; background investigations; employment suitability policy; access determination; rules of behavior/ conduct; termination procedures; non-disclosure agreements.
Physical Security Policies and Procedures	Internal/external access control; protective services; identification/badging; visitor access controls; parking areas and access control; perimeter fencing/barriers; shipping, receiving and transport; security lighting; restricted areas; signage; intrusion detection systems; alarm monitoring/response; closed circuit television; product storage security; other control measures.
Information Security	Identification of sensitive information; access control; storage of information; document control; retention/ destruction requirements.
Information Technology/Cyber Security Policies and Procedures	Intrusion detection and prevention systems; threat identification; employee training; encryption systems; identification of sensitive information/media; password policy; removable media policy; laptop policy; access control and determination; system document control; system backup; system disaster recovery; incident response;

	system audit procedures; property accountability.
3. Site Security Master Plan	
The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; bio-containment laboratories	
4. Site Threat / Vulnerability / Risk Assessment	
The partner facility shall provide a written risk assessment for the facility addressing: criminal threat; terrorist threat; industrial espionage; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies.	
5. Physical Security	
Closed Circuit Television (CCTV) Monitoring	Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. CCTV coverage should include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup.
Facility Lighting	Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. Lighting must have emergency power backup. Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	Should have CCTV coverage and an electronic access control system. Should have procedures in place to control access and movement of drivers picking up or delivering shipments. Must identify drivers picking up BARDA products by government issued photo identification.
Access Control	Should have an electronic intrusion detection system with centralized monitoring. Responses to alarms must be immediate and documented in writing. Employ an electronic system (i.e. card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production

	facilities, warehouses, server rooms, records storage, etc.) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. Should have procedures to prevent employee piggybacking. Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Should have a manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property. Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program and the potential threat environment.
Protective Security Forces	Requirements for a security force will be determined by the criticality of the program and the potential threat environment.
6. Security Operations	
Information Sharing	Establish formal liaison with law enforcement and implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage security of the facility. Ensure subOfferor compliance with BARDA security requirements.
7. Personnel Security	
Records Checks	Verification of date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, and local

	/ national criminal history search.
Hiring and Retention Standards	Policies and procedures concerning hiring, and retention of employees to include employee conduct expectations.
8. Information Security	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary or with appropriate government markings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet / desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents shall be destroyed using approved destruction measures (i.e. shredders / approved third party vendors / pulverizing / incinerating).
9. Information Technology & Cybersecurity	
Access Control	Limit information systems access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Ensure the actions of individual information system users can be uniquely traced to those users.
Configuration Management	Establish and enforce security configuration settings.
Contingency Planning	Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.

Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.
Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards.
Network Protection	Employ intrusion prevention and detection technology.
10. Transportation Security	
Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers should be vetted in accordance with BARDA Personnel Security Requirements. Drivers should be trained on specific security and emergency procedures. Drivers should be equipped with backup communications. Driver identity should be 100 percent confirmed before pick-up of any BARDA product. Drivers should never leave BARDA product unattended and two drivers may be required for longer transport routes or critical products during times of emergency.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, large planned events, weather, and other situations that may delay or disrupt transport.
Product Security	BARDA products should be secured with tamper resistant seals during transport and

	the transport trailer should be locked and sealed. Tamper resistant seals should be verified as “secure” after the product is placed in the transport vehicle. BARDA product should be continually monitored by GPS technology while in transport and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
11. Security Reporting Requirements	
The partner facility shall immediately report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
12. Security Audits	
The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub locations.	

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT ***Note: Complete this Form in Accordance with Accompanying Instructions.***	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at End of Prior Period**	**Incurred Cost-- Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Negotiated Contract Amount**	**Variance (Over or Under) (I - H)**
	Negotiated	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

INSTRUCTIONS FOR COMPLETING FORM "FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by BARDA in monitoring the application of financial and personnel resources to the BARDA contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analysis of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate form, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and
(iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:	**CONTRACT NUMBER:**
ADDRESS:	**REPORT DATE:**
ADDRESS1:	
ADDRESS2:	**FISCAL YEAR:**
CITY:	
STATE:	
ZIP:	

CLASSIFICATION	**BEGINNING OF PERIOD**		**ADJUSTMENTS**			**END OF PERIOD**	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST >=$25K							
PROPERTY UNDER CONST <$25K							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING >=$25K							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP >=$25K							
SPECIAL TEST EQUIP <$25K							
AGENCY PECULIAR >=$25K							
AGENCY PECULIAR <$25K							
MATERIAL >=$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							

SIGNED BY:			
SIGNATURE		DATE SIGNED:	
NAME PRINTED		Email	
TITLE		TELEPHONE	

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael A. Sherman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended September 30, 2022 of Chimerix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2022

/s/ Michael A. Sherman

Michael A. Sherman
President & Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF 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, 2022 of Chimerix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2022

/s/ Michael T. Andriole
Michael T. Andriole
Chief Business and Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Chimerix, Inc. (the "Company") for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Sherman, as Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2022

/s/ Michael A. Sherman
Michael A. Sherman
President & Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Chimerix, Inc. (the "Company") for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael T. Andriole, as Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2022

/s/ Michael T. Andriole
Michael T. Andriole
Chief Business and Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES
		1 1

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ NO	5. PROJECT NO (*if applicable*)
P00001	See Block 16C	N/A.	

6. ISSUED BY CODE	ASPR-BARDA	7. ADMINISTERED BY (*if other than line item 6*) CODE	ASPR-BARDA02
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR (*No, street, county, State and ZIP Code*)	(x)	9A AMENDMENT OF SOLICITATION NO.
CHIMERIX, INC. 1377270 CHIMERIX, INC. 2505 MERIDIAN P 2505 MERIDIAN PKWY STE 340 DURHAM NC 277135246		9B DATED (*SEE ITEM 11*)
	X	10A MODIFICATION OF CONTRACT/ORDER NO 75A50122C00047
CODE 1377270 FACILITY CODE		10B DATED (*SEE ITEM 13*) 08/26/2022

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified of receipt of Offers is extended. is not extended
Offers must acknowledge receipt of this amendment prior to the hour end dale specified in the solicitation or as amended, by one or the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*if required*)
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO IN ITEM 10A
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF
	D. OTHER (*Specify type of modification and authority*)

E. IMPORTANT: Contractor is not. is required to sign this document and return 0 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

Tax ID Number: 33-0903395

DUNS Number: 121785997

UEI: KLDQF5TYQM45

Smallpx Antiviral

The purpose of this administrative change notice is to change the Contracting Officer to Jonathan Gonzalez.

The Statement of Work under the contract hereby remains unchanged. The total amount and scope as well as ll other terms and conditions of the contract remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)	
Michael Alrutz		JONATHAN F. GONZALEZ	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Michael Alrutz (*Signature of person authorized to sign*)	9/9/2022	/s/ Jonathan F. Gonzalez (*Signature of person authorized to sign*)	9/8/22

Previous edition unusable

STANDARD FROM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243