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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to

Commission file number: 001-38663

Gritstone bio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-4859534**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
5959 Horton Street, Suite 300 Emeryville, California	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

(510) 871-6100
(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, $0.0001 par value per share	**GRTS**	**The Nasdaq Global Select 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 ☒ 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 ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
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. ☒

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

As of November 6, 2023, there were 95,342,055 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

Gritstone bio, Inc.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Gritstone bio, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

(In thousands, except share amounts and par value)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 29,539	$ 55,498
Marketable securities	54,409	116,389
Restricted cash	1,242	3,977
Prepaid expenses and other current assets	5,630	7,014
Total current assets	90,820	182,878
Long-term restricted cash	5,290	5,290
Property and equipment, net	18,952	21,335
Lease right-of-use assets	70,909	17,481
Deposits and other long-term assets	1,246	9,739
Long-term marketable securities	—	4,031
Total assets	$ 187,217	$ 240,754
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,265	$ 8,694
Accrued compensation	7,772	8,215
Accrued liabilities	1,660	4,124
Accrued research and development expenses	2,382	3,343
Lease liabilities, current portion	6,003	5,294
Deferred revenue, current portion	1,301	5,131
Total current liabilities	23,383	34,801
Other liabilities, noncurrent	554	150
Lease liabilities, net of current portion	59,430	15,673
Debt, noncurrent	29,868	19,349
Total liabilities	113,235	69,973
Commitments and contingencies (Notes 6, 8 and 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at September 30, 2023 and December 31, 2022; 93,075,427 and 86,894,901 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	22	22
Additional paid-in capital	702,755	691,910
Accumulated other comprehensive loss	(52)	(80)
Accumulated deficit	(628,743)	(521,071)
Total stockholders' equity	73,982	170,781
Total liabilities and stockholders' equity	$ 187,217	$ 240,754

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration and license revenues	$ 361	$ 436	$ 1,302	$ 7,942
Grant revenues	1,204	2,585	4,659	7,741
Total revenues	1,565	3,021	5,961	15,683
Operating expenses:				
Research and development	32,763	26,436	94,244	81,983
General and administrative	7,406	6,462	20,867	22,209
Total operating expenses	40,169	32,898	115,111	104,192
Loss from operations	(38,604)	(29,877)	(109,150)	(88,509)
Interest income	1,167	462	4,324	663
Interest expense	(991)	(551)	(2,818)	(551)
Other expense	(6)	—	(28)	—
Net loss	(38,434)	(29,966)	(107,672)	(88,397)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	73	129	28	(208)
Comprehensive loss	$ (38,361)	$ (29,837)	$ (107,644)	$ (88,605)
Net loss per share, basic and diluted	$ (0.33)	$ (0.35)	$ (0.94)	$ (1.02)
Weighted-average number of shares used in computing net loss per share, basic and diluted	115,342,613	86,597,405	114,898,379	86,441,212

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

(In thousands, except share amounts)

Three Months Ended September 30, 2023:

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at June 30, 2023	91,224,210	$ 22	$ 699,979	$ (125)	$ (590,309)	$ 109,567
Issuance of common stock upon restricted stock units vesting	202,317	—	—	—	—	—
Issuance of common stock for warrant exercises	1,648,900	—	16	—	—	16
Tax payments related to shares withheld for vested restricted stock units	—	—	(204)	—	—	(204)
Stock-based compensation	—	—	2,964	—	—	2,964
Unrealized gain on marketable securities	—	—	—	73	—	73
Net loss	—	—	—	—	(38,434)	(38,434)
Balance at September 30, 2023	93,075,427	$ 22	$ 702,755	$ (52)	$ (628,743)	$ 73,982

Three Months Ended September 30, 2022:

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at June 30, 2022	73,006,089	$ 20	$ 623,583	$ (410)	$ (459,815)	$ 163,378
Issuance of common stock under the ATM equity offering program, net of issuance costs of $48	95,000	—	197	—	—	197
Issuance of common stock upon exercise of stock options	32,962	—	45	—	—	45
Stock-based compensation	—	—	3,064	—	—	3,064
Unrealized gain on marketable securities	—	—	—	129	—	129
Net loss	—	—	—	—	(29,966)	(29,966)
Balance at September 30, 2022	73,134,051	$ 20	$ 626,889	$ (281)	$ (489,781)	$ 136,847

Continued on next page.

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

(In thousands, except share amounts)

Nine Months Ended September 30, 2023:

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at December 31, 2022	86,894,901	$ 22	$ 691,910	$ (80)	$ (521,071)	$ 170,781
Issuance of common stock under the ATM equity offering program, net of issuance costs of $79	854,052	—	2,525	—	—	2,525
Issuance of common stock upon restricted stock units vesting	547,980	—	—	—	—	—
Tax payments related to shares withheld for vested restricted stock units	—	—	(946)	—	—	(946)
Issuance of common stock upon exercise of stock options	6,000	—	5	—	—	5
Issuance of common stock for warrant exercises	4,498,305	—	16	—	—	16
Issuance of common stock under the ESPP	274,189	—	450	—	—	450
Stock-based compensation	—	—	8,795	—	—	8,795
Unrealized gain on marketable securities	—	—	—	28	—	28
Net loss	—	—	—	—	(107,672)	(107,672)
Balance at September 30, 2023	93,075,427	$ 22	$ 702,755	$ (52)	$ (628,743)	$ 73,982

Nine Months Ended September 30, 2022:

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at December 31, 2021	69,047,878	$ 20	$ 617,523	$ (73)	$ (401,384)	$ 216,086
Issuance of common stock under the ATM equity offering program, net of issuance costs of $48	95,000	—	197	—	—	197
Issuance of common stock for warrant exercises	3,442,567	—	34	—	—	34
Issuance of common stock upon restricted stock units vesting	215,350	—	—	—	—	—
Tax payments related to shares withheld for vested restricted stock units	—	—	(890)	—	—	(890)
Issuance of common stock upon exercise of stock options	140,000	—	145	—	—	145
Issuance of common stock under the ESPP	193,256	—	331	—	—	331
Stock-based compensation	—	—	9,549	—	—	9,549
Unrealized loss on marketable securities	—	—	—	(208)	—	(208)
Net loss	—	—	—	—	(88,397)	(88,397)
Balance at September 30, 2022	73,134,051	$ 20	$ 626,889	$ (281)	$ (489,781)	$ 136,847

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net loss	$ (107,672)	$ (88,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,670	4,769
Net amortization of premiums and discounts on marketable securities	(2,388)	278
Amortization of debt discount and issuance costs	938	127
Stock-based compensation	8,795	9,549
Non-cash operating lease expense	10,279	6,891
Loss on disposition of property and equipment	21	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,384	781
Deposits and other long-term assets	4,297	(3,180)
Accounts payable	(1,384)	(943)
Accrued compensation	(443)	(217)
Accrued and other non-current liabilities	(3,368)	1,543
Accrued research and development expenses	428	1,331
Lease liability	(14,867)	(6,463)
Deferred revenue	(3,830)	(11,641)
Net cash used in operating activities	(102,140)	(85,572)
Investing activities		
Purchase of marketable securities	(22,681)	(64,641)
Maturities of marketable securities	91,108	102,218
Purchase of property and equipment	(4,381)	(4,389)
Net cash provided by investing activities	64,046	33,188
Financing activities		
Proceeds from issuance of common stock upon exercise of stock options, warrants, and other	21	179
Proceeds from issuance of common stock from the ATM equity offering program	2,604	245
Proceeds from long-term debt, net of debt discount and issuance costs	9,962	19,154
Proceeds from issuance of common stock under the ESPP	450	331
Payments of financing costs	(2,512)	(115)
Payments of financing lease	(179)	(171)
Tax payments related to shares withheld for vested restricted stock units	(946)	(890)
Net cash provided by financing activities	9,400	18,733
Net decrease in cash, cash equivalents and restricted cash	(28,694)	(33,651)
Cash, cash equivalents and restricted cash at beginning of period	64,765	110,577
Cash, cash equivalents and restricted cash at end of period	$ 36,071	$ 76,926
Supplemental disclosures of non-cash investing and financing information		
Property and equipment purchases accrued but not yet paid	$ 72	$ 1,174
Financing costs included in accrued liabilities and accounts payable	$ —	$ 2
Remeasurement of operating lease right-of-use asset for lease modification	$ 706	$ 1,406
Cash paid for interest on debt	$ 1,746	$ 208
Assets acquired under leasing obligations	$ 59,604	$ 553

See accompanying notes to the unaudited condensed consolidated financial statements.

1. Organization

Description of Business

Gritstone bio, Inc. (“Gritstone” or “the Company”) is a clinical stage biotechnology company that aims to develop the world's most potent vaccines. The Company was incorporated in the state of Delaware in August 2015, and is based in Emeryville, California and Boston, Massachusetts, with a manufacturing facility in Pleasanton, California. The Company operates in one segment.

Liquidity

The Company has incurred operating losses and has an accumulated deficit as a result of ongoing efforts to develop drug product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. To date, none of the Company’s product candidates have been approved for sale and therefore the Company has not generated any revenue from sales of commercial products. Management expects operating losses to continue for the foreseeable future. The Company has funded its operations to date primarily through private placements of its convertible preferred stock, common stock, and pre-funded warrants, the sale of common stock in public offerings and under its “at the market” offering programs, and through proceeds received from its collaboration arrangements. The Company had net losses of $38.4 million and $107.7 million for the three and nine months ended September 30, 2023, respectively, and $30.0 million and $88.4 million for the three and nine months ended September 30, 2022, respectively. Cash used by operating activities was $102.1 million and $85.6 million during the nine months ended September 30, 2023 and 2022, respectively. The Company had an accumulated deficit of $628.7 million and $521.1 million as of September 30, 2023 and December 31, 2022, respectively. As of September 30, 2023, the Company had cash, cash equivalents and marketable securities of $83.9 million. The Company’s cash, cash equivalents and marketable securities are not sufficient to fund the Company’s planned operations for a period of 12 months from the date these condensed consolidated financial statements are issued. To fund the Company's planned operations, the Company will need to raise additional capital. The Company intends to raise additional capital through private and public equity offerings, including its “at-the-market” offering programs, debt financings, and potential future collaboration, license and development agreements. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms acceptable to the Company or at all. If the Company is unsuccessful in its efforts to raise additional capital or if sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate one or more of its development programs or its future commercialization efforts, out-license intellectual property rights to its product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the Company’s business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all. Failure to manage discretionary spending or raise additional capital, as needed, may adversely impact the Company’s ability to achieve its intended business objectives. These conditions raise substantial doubt about the Company’s ability to continue as a going concern for a period of one year from the date of the issuance of these condensed consolidated financial statements. The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited and are comprised of the consolidation of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have

been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

The accompanying interim condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim reporting.

The interim condensed consolidated financial statements are unaudited and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation for interim reporting. The results of operations for any interim period are not necessarily indicative of results of operations for any future period.

Certain information and footnote disclosures typically included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements as of and for the year ended December 31, 2022, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 9, 2023.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Fair Value of Financial Instruments

U.S. GAAP establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is established as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, an established three-tier fair value hierarchy distinguishes between the following:

- Level 1 inputs are quoted prices in active markets that are accessible at the market date for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the assets or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value instrument.

The carrying amounts reflected on the condensed consolidated balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued compensation and accrued liabilities approximate their fair values due to their short-term nature.

Debt Issuance Costs and Debt Discounts

Debt issuance costs include legal fees, accounting fees and other direct costs incurred in connection with the execution of the Company's debt financing. Debt discounts represent costs paid to the lenders. Debt issuance costs and debt discounts are deducted from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt using the effective interest method.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents and marketable securities. Cash, cash equivalents and marketable securities are invested through banks and other financial institutions in the United States. Such deposits may be in excess of federally insured limits. The Company maintains cash equivalents and marketable securities with various high-credit-quality and capitalized financial institutions. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the condensed consolidated balance sheets. As of September 30, 2023, the Company has no off-balance sheet concentrations of credit risk.

Other Risks and Uncertainties

The Company is subject to a number of risks similar to those faced by other clinical-stage biotechnology companies, including dependence on key individuals; the need to develop commercially viable therapeutics; competition from other companies, many of which are larger and better capitalized; and the need to obtain adequate additional financing to fund the development of its products. The Company currently depends on third-party suppliers for key materials and services used in its research and development manufacturing process and is subject to certain risks related to the loss of these third-party suppliers or their inability to supply the Company with adequate materials and services. Further, the Company is subject to broad market risks and uncertainties resulting from recent events, such as the lingering effects of the COVID-19 pandemic, the regional conflicts around the world, inflation, rising or sustained high interest rates and recession risks, market volatility, recent instability in the global financial markets and uncertainty as to the U.S. federal budget, as well as supply chain and labor shortages.

Cash, Cash Equivalents and Restricted Cash

Cash equivalents, which consist primarily of highly liquid investments with original maturities of three (3) months or less when purchased, are stated at fair value. These assets include investments in money market funds that invest in U.S. Treasury obligations and certificates of deposit, which are stated at fair value.

The Company has issued letters of credit under certain lease agreements that have been collateralized by cash deposits for an equal amount and are recorded within short-term restricted cash and deposits and other long-term assets on the condensed consolidated balance sheets based on the term of the underlying lease. Additionally, the Company's restricted cash includes payments received under the Coalition for Epidemic Preparedness Innovations ("CEPI") Funding Agreement, dated as of August 14, 2021 (the "CEPI Funding Agreement") and the Gates Foundation Grant

Agreement (see Note 9). The Company will utilize the CEPI and Gates Foundation funds as it incurs expenses for services performed under the agreements.

The following table provides a reconciliation of cash, cash equivalents and short-term and long-term restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows (in thousands):

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 29,539	$ 55,498
Restricted cash	1,242	3,977
Long-term restricted cash	5,290	5,290
Total cash, cash equivalents and restricted cash	$ 36,071	$ 64,765

Leases

The Company determines whether the arrangement is or contains a lease at the inception of the arrangement and if such a lease is classified as a financing lease or operating lease. The majority of the Company's leases are classified as operating leases. Leases with a term greater than one year are included in operating lease right-of-use assets ("ROU Assets"), lease liabilities, current portion, and lease liabilities, net of current portion in the Company's condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022. The Company has elected not to recognize on the condensed consolidated balance sheets leases with terms of one year or less. Lease liabilities and their corresponding ROU Assets are recorded based on the present value of lease payments over the expected lease term. In determining the net present value of lease payments, the interest rate implicit in lease contracts is typically not readily determinable. As such, the Company estimates the appropriate incremental borrowing rate, which is the rate that would be incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the ROU Assets may be required for items such as initial direct costs paid or incentives received and impairment charges if the Company determines the ROU Asset is impaired.

The Company considers a lease term to be the non-cancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The Company recognizes lease expense on a straight-line basis over the expected lease term.

The Company has elected not to separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component. The lease components resulting in an ROU Asset have been recorded on the condensed consolidated balance sheets and amortized as lease expense on a straight-line basis over the lease term.

Revenue Recognition

The Company performs research and development activities under collaboration, license, grant and clinical development agreements. The Company's revenue primarily consists of revenue from collaboration and license agreements and grant agreements. At contract inception, the Company analyzes a revenue arrangement to determine the appropriate accounting under U.S. GAAP. Currently, the Company's revenue arrangements represent customer contracts within the scope of ASC Topic 606, Revenue from Contracts with Customers ("ASC 606") or are subject to the contribution guidance in ASC Topic 958-605, Not-for-Profit Entities – Revenue Recognition ("ASC 958-605"), which applies to business entities that receive contributions within the scope of ASC 958-605.

For collaboration and license agreements, the Company analyzes such arrangements to assess whether they involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements that are considered to be in the scope of the collaboration guidance and that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of the collaboration guidance and those that are more reflective of a vendor-customer relationship and, therefore,

within the scope of the revenue with contracts with customers guidance. Elements of collaboration arrangements that are reflective of a vendor-customer relationship are accounted for pursuant to the revenue from contracts with customers guidance. The terms of the licensing and collaboration agreements entered into typically include payment of one or more of the following: non-refundable, up-front fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues. The core principle of the accounting for revenue from contracts with customers guidance is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received in exchange for those goods or services.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's condensed consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve (12) months, this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in the Company's condensed consolidated balance sheets. If the Company expects to have an unconditional right to receive consideration in the next twelve (12) months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

At contract inception, the Company assesses the goods or services promised in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.

The Company considers the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations, based on the relative standalone selling prices. The relative selling price for each performance obligation is estimated using objective evidence if it is available. If objective evidence is not available, the Company uses its best estimate of the selling price for the performance obligation.

Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset, which for a service is considered to be as the services are received and used. The Company recognizes revenue over time by measuring the progress toward complete satisfaction of the relevant performance obligation, using an appropriate input or output method based on the nature of the good or service promised to the customer.

After contract inception, the transaction price is reassessed at every period end and updated for changes, such as resolution of uncertain events. Any change in the transaction price is allocated to the performance obligations on the same basis as at contract inception.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the stand-alone selling prices of identified performance obligations (which may include forecasted revenue, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success) and estimating the progress towards satisfaction of performance obligations.

For grant funding agreements, grant revenue is recognized during the period that the research and development services occur, as qualifying expenses are incurred. The Company concluded that payments received under its grant funding agreements represent nonreciprocal contributions, as described in ASC 958, Not-for-Profit Entities, and that the grants are not within the scope of ASC 606 as the organization providing the grant does not meet the definition of a customer. Grant revenue relates primarily to the CEPI Funding Agreement and the Gates Grant Agreement (see Note 9).

Income Taxes

The Company did not record income tax expense for the three and nine months ended September 30, 2023 and 2022, respectively, as the Company expected to be in a cumulative taxable loss position in 2023 and 2022, and the net deferred tax assets are fully offset by a valuation allowance as it is not more likely than not that the benefit will be realized. As of September 30, 2023, the Company remains in a cumulative book loss position and does not have sufficient positive evidence to realize its net deferred tax assets. As such, the Company continues to maintain a full valuation allowance against its net deferred tax assets.

Effective January 1, 2022, a provision of the Tax Cuts and Jobs Act (TCJA) took effect creating a significant change to the treatment of research and experimental expenditures under Section 174 of the Internal Revenue Code (Sec. 174 expenses). Historically, businesses have had the option of deducting Sec. 174 expenses in the year incurred or capitalizing and amortizing the costs over five years. The new TCJA provision, however, eliminates this option and will require Sec. 174 expenses associated with research conducted in the United States to be capitalized and amortized over a five-year period. For expenses associated with research outside of the United States, Sec. 174 expenses will be capitalized and amortized over a 15-year period. This provision did not have a material impact to the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt - Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASU 2020-06"). The standard eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the standard modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for the Company as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company does not expect the adoption of ASU 2020-06 to have a material impact on its condensed consolidated financial statements and related disclosures.

3. Cash Equivalents and Marketable Securities

The amortized costs, unrealized gains and losses and fair values of cash equivalents and marketable securities were as follows (in thousands):

	September 30, 2023			
Description	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Cash equivalents:				
Money market funds	$ 15,883	$ —	$ —	$ 15,883
Total cash equivalents	15,883	—	—	15,883
Short-term marketable securities:				
Commercial paper	11,871	—	(8)	11,863
Corporate debt securities	9,306	—	(12)	9,294
U.S. government treasuries	13,885	—	(12)	13,873
U.S. government debt securities	18,904	—	(20)	18,884
Asset backed securities	495	—	—	495
Total short-term marketable securities	54,461	—	(52)	54,409
Total	$ 70,344	$ —	$ (52)	$ 70,292

Description	December 31, 2022 Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	$ 38,191	$ —	$ —	$ 38,191
Total cash equivalents	38,191	—	—	38,191
Short-term marketable securities:				
Certificates of deposit	948	1	—	949
Commercial paper	33,318	23	(13)	33,328
Corporate debt securities	21,887	6	(40)	21,853
U.S. government treasuries	35,608	3	(71)	35,540
U.S. government debt securities	24,703	22	(6)	24,719
Total short-term marketable securities	116,464	55	(130)	116,389
Long-term marketable securities:				
Corporate debt securities	933	—	(1)	932
U.S. government treasuries	3,103	—	(4)	3,099
Total long-term marketable securities	4,036	—	(5)	4,031
Total	$ 158,691	$ 55	$ (135)	$ 158,611

All marketable securities held as of September 30, 2023 had contractual maturities of less than one year. There have been no material realized gains or losses on marketable securities for the periods presented. As of September 30, 2023, the Company did not hold any individual securities in an unrealized loss position for 12 months or greater. The Company has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. No significant facts or circumstances have arisen to indicate that there has been any significant deterioration in the creditworthiness of the issuers of the securities held by us. The Company considered the current and expected future economic and market conditions and determined that the estimate of credit losses was not significantly impacted. Thus, there has been no change in estimate of expected credit loss during the three and nine months ended September 30, 2023 and 2022 and no allowance for credit loss was recorded at September 30, 2023 and December 31, 2022. The Company will continue to assess the current and expected future economic and market conditions as further development arises.

See Note 4 for further information regarding the fair value of the Company's financial instruments.

4. Fair Value Measurements

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows (in thousands):

Description	September 30, 2023 Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 15,883	$ 15,883	$ —	$ —
Total cash equivalents	15,883	15,883	—	—
Short-term marketable securities:				
Commercial paper	11,863	—	11,863	—
Corporate debt securities	9,294	—	9,294	—
U.S. government treasuries	13,873	13,873	—	—
U.S. government debt securities	18,884	—	18,884	—
Asset backed securities	495	—	495	—
Total short-term marketable securities	54,409	13,873	40,536	—
Total	$ 70,292	$ 29,756	$ 40,536	$ —

Description	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 38,191	$ 38,191	$ —	$ —
Total cash equivalents	38,191	38,191	—	—
Short-term marketable securities:				
Certificates of deposit	949	—	949	—
Commercial paper	33,328	—	33,328	—
Corporate debt securities	21,853	—	21,853	—
U.S. government treasuries	35,540	35,540	—	—
U.S. government debt securities	24,719	—	24,719	—
Total short-term marketable securities	116,389	35,540	80,849	—
Long-term marketable securities:				
Corporate debt securities	932	—	932	—
U.S. government treasuries	3,099	3,099	—	—
Total long-term marketable securities	4,031	3,099	932	—
Total	$ 158,611	$ 76,830	$ 81,781	$ —

The Company measures the fair value of money market funds and U.S. government treasuries based on quoted prices in active markets for identical securities. Commercial paper, corporate debt securities, certificates of deposits, asset backed securities, and U.S. government debt securities are valued taking into consideration valuations obtained from third-party pricing services. These pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of, and broker/dealer quotes on, the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

There were no transfers between Level 1 and Level 2 during the periods presented. See Note 3 for further information regarding the amortized cost of the Company's financial instruments.

5. Property and Equipment, Net

Property and equipment and related accumulated depreciation and amortization are as follows (in thousands):

	September 30, 2023	December 31, 2022
Computer equipment and software	$ 1,723	$ 1,155
Furniture and fixtures	3,064	2,285
Laboratory equipment	29,356	27,309
Leasehold improvements	18,600	18,024
	52,743	48,773
Less accumulated depreciation and amortization	(33,819)	(28,782)
Construction-in-progress	28	1,344
Total property and equipment, net	$ 18,952	$ 21,335

Depreciation and amortization expense was $2.0 million and $5.7 million for the three and nine months ended September 30, 2023, respectively, and $1.7 million and $4.8 million for the three and nine months ended September 30, 2022, respectively.

6. Commitments and Contingencies

Leases

The Company leases office, laboratory and storage space in facilities at several locations:

Emeryville Lease

The Company's principal executive offices in Emeryville, California, consisting of office and laboratory space, are leased pursuant to a 120-month operating lease (the "Emeryville Lease"), which the Company entered into in January 2019, with the obligation to pay rent commencing in November 2019. In conjunction with signing the Emeryville Lease, the Company paid a cash security deposit of $0.6 million, which is recorded as a deposit on the Company's condensed consolidated balance sheet as of September 30, 2023. The Emeryville Lease includes a free rent period, an escalation clause for increased rent and a renewal provision allowing the Company to extend this lease for two additional five-year periods at the then market rental rate. The lessor provided the Company a tenant improvement allowance for a total of $4.0 million to complete the laboratory and office renovation. The Company has determined the tenant improvements to be lessee owned and therefore has recorded a $7.5 million ROU Asset and a $11.9 million lease liability on the condensed consolidated balance sheet as of September 30, 2023. The Company recorded a $8.1 million ROU Asset and a $12.8 million lease liability on the consolidated balance sheet as of December 31, 2022.

Pleasanton Leases

The Company leases 42,620 square feet of office, cleanroom, and laboratory support manufacturing space in Pleasanton, California pursuant to a non-cancelable operating lease (the "Pleasanton Lease"), which the Company entered into in March 2017, with the obligation to pay rent commencing in December 2017. The Pleasanton Lease includes a free rent period, escalating rent payments and a term that expires on November 30, 2024. The Company may extend the lease term once for a period of five years at the then market rental rate. The Company obtained an irrevocable letter of credit in March 2017 in the initial amount of approximately $1.0 million as a security deposit for the Pleasanton Lease, which may be drawn down by the landlord in the event the Company fails to fully and faithfully perform its obligations under the Pleasanton lease. The letter of credit may be reduced based on certain levels of cash and cash equivalents the Company holds. In October 2022, the letter of credit was reduced to a balance of $0.6 million. As of September 30, 2023, none of the irrevocable letter of credit amount had been drawn. The Pleasanton Lease further provides that the Company is obligated to pay to the landlord its proportionate share of certain basic operating costs, including taxes and operating expenses.

In connection with the Pleasanton Lease, the Company received a tenant improvement allowance of $1.2 million from the landlord for the costs associated with the design, development and construction of tenant improvements. The unamortized tenant improvement balance is recognized as a component of operating lease ROU Assets on the condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022.

In addition, in May 2019, the Company entered into a 64-month non-cancelable operating lease for additional office space in Pleasanton, California, with an obligation to pay rent commencing in August 2019. In January 2022, the Company amended the lease to add additional leased space and extend the lease expiration date to February 2027.

Cambridge Leases

The Company leases laboratory, office and storage space in several facilities in Cambridge, Massachusetts, pursuant to three separate agreements:

The Company's facility located at 40 Erie Street in Cambridge, Massachusetts is leased pursuant to a 67-month non-cancelable operating lease (as amended, the "40 Erie Lease"), which the Company entered into in February 2016, with an obligation to pay rent commencing in October 2016. The lessor provided the Company a tenant improvement allowance for a total of $2.1 million to complete the laboratory and office renovation. In September 2021, the Company executed an amendment to the 40 Erie Lease, which extends its term through April 2025 and provides for monthly base rent amounts, subject to annual increases over the term of the lease.

The Company's facility located at 21 Erie Street in Cambridge, Massachusetts is leased pursuant to a 24-month non-cancelable operating lease (as amended, the "21 Erie Lease"), which the Company entered into in September

2018. The 21 Erie Lease has since been amended five times, as a result of which the lease term extends through June 2023.

In March 2021, the Company entered into a 17-month operating lease (as amended, the "Cambridge Storage Lease") for additional office and laboratory storage space in Cambridge, Massachusetts, which commenced on April 1, 2021. The Company also paid an insignificant cash security deposit. The Cambridge Storage Lease was amended in June 2022 to extend the lease term through June 30, 2023.

In conjunction with the 40 Erie Lease, the 21 Erie Lease and the Cambridge Storage Lease, each as amended (if applicable), the Company has paid certain cash security deposits, which in each case included amounts for the applicable last month's rent and has been classified as part of the operating lease ROU Assets. As of September 30, 2023, of the $0.3 million security deposits, less than $0.1 million was recorded in prepaid expenses and other current assets and the remaining $0.3 million was recorded in deposits and other long-term assets on the Company's condensed consolidated balance sheet. As of December 31, 2022, of the $0.7 million security deposits, $0.4 million was recorded in prepaid expenses and other current assets and the remaining $0.3 million was recorded in deposits and other long-term assets on the Company's condensed consolidated balance sheet.

Boston Lease

The Company occupies a newly built facility in Boston, Massachusetts, with office and laboratory space, pursuant to a 120-month operating lease (as amended, the "Boston Lease"), which the Company entered into in September 2021. The Boston Lease includes a free rent period, an escalation clause for increased rent and a renewal provision allowing the Company to extend the Boston Lease for two additional five-year periods at the then market rental rate. The landlord provided the Company with a tenant improvement allowance of up to approximately $19.1 million for costs relating to the design, permitting and construction of improvements owned by the landlord. The Company incurred tenant improvement costs relating to the initial design and construction of the improvements before the commencement date which were accounted for as lease prepayments. The Company's obligation to pay rent commenced in July 2023, subject to free rent periods of three and nine months with respect to certain premises. The Company was provided early access to the premises to install fixtures and equipment 60 days prior to the anticipated rent commencement date. The Boston Lease expires in 2033. Under the Boston Lease, the Company is obligated to pay to the landlord its proportionate share of certain basic operating costs, including taxes and operating expenses. As a security deposit under the Boston Lease, the Company provided the landlord an irrevocable letter of credit in the amount of approximately $4.6 million, which is collateralized by a restricted cash deposit of $4.7 million, and which may be reduced in the fifth and seventh years of the Boston Lease. As of September 30, 2023, none of the irrevocable letter of credit amount had been drawn.

The Boston Lease commenced in April 2023, when the Company was provided early access to the premises and gained control over the use of the underlying assets. Upon commencement, the Company recognized an ROU Asset of $59.3 million and a lease liability of $50.9 million on the condensed consolidated balance sheet. Upon commencement, the ROU Asset includes $8.4 million of lease prepayments made before the commencement date, which are primarily related to the lessor owned tenant improvement cost.

In September 2023, the Company amended the Boston Lease, whereby the lease term commenced on July 1, 2023 and expires on June 30, 2033.

The Company's operating leases include various covenants, indemnities, defaults, termination rights, security deposits and other provisions customary for lease transactions of this nature.

The components of lease costs, which were included in the Company's condensed consolidated statements of operations and comprehensive loss, were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Lease cost				
Operating lease cost	$ 3,370	$ 2,112	$ 9,970	$ 6,633
Short-term lease cost	12	—	12	—
Total lease cost	$ 3,382	$ 2,112	$ 9,982	$ 6,633

Supplemental information related to leases was as follows:

	Nine Months Ended September 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities (in thousands):		
Operating cash flows from operating leases	$ 14,867	$ 6,467
New right-of-use assets obtained in exchange for lease obligations (in thousands):		
Right-of-use assets obtained from entering new leases	$ 59,604	$ 553
Increase in right-of-use assets from lease modifications	$ 706	$ 1,406
Weighted-average remaining lease term (years):		
Operating leases	8.5	5.0
Weighted-average discount rate:		
Operating leases	10.0%	7.5%

As of September 30, 2023, minimum annual rental payments under the Company's lease agreements are as follows (in thousands):

	Lease Financing Obligation
Year ending December 31,	
2023 (remaining three months)	$ 2,369
2024	12,834
2025	10,749
2026	10,376
2027	10,466
Thereafter	52,348
Total minimum payments	99,142
Less: Amounts representing interest expense	(33,709)
Present value of future minimum lease payments	65,433
Less: Current portion of lease liability	(6,003)
Noncurrent portion of lease liability	$ 59,430

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its amended and restated certificate of incorporation and amended and restated bylaws, and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, with respect to which the officer or director is or was serving in such capacity at the Company's request. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

7. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	September 30, 2023	December 31, 2022
Prepaid research and development-related expenses	$ 4,370	$ 4,241
Collaboration receivable	47	135
Prepaid insurance	83	1,158
Interest and other receivables	290	529
Facilities-related deposits	16	384
Other	824	567
Total prepaid expenses and other current assets	$ 5,630	$ 7,014

Deposits and Other Long-Term Assets

Deposits and other long-term assets consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Lease security deposits	$ 923	$ 934
Prepaid research and development-related expenses	—	643
Prepaid rent	323	8,162
Total deposits and other long-term assets	$ 1,246	$ 9,739

8. Debt

In July 2022, the Company entered into a loan and security agreement (as amended, the "Loan Agreement") with Hercules Capital, Inc. ("Hercules") and Silicon Valley Bank ("SVB"), which provides the Company a 60-month term loan facility for up to $80.0 million in borrowing capacity across five potential tranches. At the closing of the Loan Agreement, the Company drew $20.0 million from the first tranche and in March 2023, the Company drew an additional $10.0 million from the first tranche. The remaining tranches provide up to $50.0 million borrowing capacity and become available upon the Company meeting certain milestones set forth in the Loan Agreement. In the fourth quarter of 2022, one milestone had been achieved, which provides the Company the ability to draw up to $10.0 million through December 15, 2023. As of September 30, 2023, the additional $10.0 million remains available to be drawn by the Company. The term loan is secured by substantially all of the Company's assets, other than intellectual property. There are no warrants associated with the Loan Agreement.

Borrowings under the Loan Agreement bear interest (i) at an annual cash rate equal to the greater of (x) the lesser of (1) the prime rate (as customarily defined) and (2) 5.50%, in either case, plus 3.15%, and (y) 7.15% and (ii) at an annual payment-in-kind rate which may equal 2.00%. The Company is required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential six-month and one-year extension upon satisfaction of certain conditions. The interest-only payment date has been extended an additional six months based on the Company's achievement of one of the milestones as set forth in the Loan Agreement. In addition, the Company paid a $150,000 facility charge upon closing, and the Company must pay a facility charge equal to 0.50% of the principal amount of any borrowings made pursuant to the amounts under the last four tranches.

All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on July 19, 2027. At the Company's option, the Company may prepay all or any portion of the outstanding borrowings, plus accrued and unpaid interest thereon and fees and expenses, subject to a prepayment premium ranging from zero to 2.5%, during the first three years after closing, depending on the year of such prepayment. Upon repayment of the term loan, the Company is required to make a final payment fee to the lenders equal to 5.75% of the aggregate original principal amount of the loan. Debt issuance costs have been treated as debt discounts on the Company's consolidated balance sheet and together with the final payment are being amortized to interest expense throughout the life of the term loan using the effective interest rate method.

In March 2023, the Company entered into the First Amendment to Loan and Security Agreement, dated as of March 31, 2023, with SVB, Hercules, Hercules Capital Funding Trust 2002-1 (the "First Amendment" and the Loan Agreement as amended by the First Amendment, the "Amended Loan Agreement"), to amend the minimum liquidity requirements under the Loan Agreement, beginning on the earliest occurrence of certain milestones or April 1, 2024, and at all times thereafter, so long as the Company's market capitalization is no greater than $400.0 million, the Company is subject to a minimum liquidity requirement equal to the then outstanding balance under the Amended Loan Agreement multiplied by 0.55 or 0.45, which multiplier depends on whether the Company achieves certain performance milestones.

The Company's obligations under the Amended Loan Agreement are subject to acceleration upon the occurrence of customary events of default, including payment default, insolvency and the occurrence of certain events having a material adverse effect on the Company, including (but not limited to) material adverse effects upon the business, operations, properties, assets or financial condition of the Company and its subsidiaries, taken as a whole. As of September 30, 2023, the Company is in compliance with all covenants in the Amended Loan Agreement, as amended.

As of September 30, 2023, there were debt discounts, unamortized issuance costs and unaccreted value of the final fee of $1.9 million which were recorded as a direct deduction from the term loan on the condensed consolidated balance sheet. Interest expense related to the Amended Loan Agreement was $1.0 million and $2.8 million, respectively, for the three and nine months ended September 30, 2023. The effective interest rate on the term loan, including the amortization of the debt discount and issuance costs, and accretion of the final payment, was 13%. The components of the long-term debt balance are as follows (in thousands):

	September 30, 2023
Principal loan balance	$ 30,000
Final fee	1,725
Unamortized debt discount, issuance costs, and unaccreted value of final fee	(1,857)
Long term debt, net	$ 29,868

As of September 30, 2023, the estimated future principal payments due (excluding the final payment fee) are as follows (in thousands):

2023 (remaining three months)	$ —
2024	—
2025	6,616
2026	14,108
2027	9,276
Total principal payments	$ 30,000

9. Collaboration and License Agreements and Grant Revenue

2seventy bio, Inc.

In August 2018, the Company entered into a Research Collaboration and License Agreement with bluebird bio, Inc. ("bluebird"). In November 2021, bluebird assigned the Research Collaboration and License Agreement (the "2seventy Agreement") to its affiliate, 2seventy bio, Inc. ("2seventy"), in connection with bluebirds restructuring and subsequent spin-out of 2seventy. Under the terms of the 2seventy Agreement, the Company provides to 2seventy tumor-specific targets across several tumor types and, in certain cases, T cell receptors (TCR) directed to those targets. The Company received a non-refundable upfront payment of $20.0 million, and 2seventy also concurrently acquired 768,115 shares of the Company's Series C convertible preferred stock for $10.0 million at $13.04 per share. Per the 2seventy Agreement, 2seventy was also provided an option to acquire shares of the Company's common stock at the same price as all other investors in connection with the Company's initial public offering ("IPO"). In October 2018, 2seventy purchased 666,667 shares of the Company's common stock at the price to the public of $15.00 per share for a total of $10.0 million. Under the terms of the 2seventy Agreement, the Company is eligible to earn development, regulatory, and sales-based milestones in an amount of up to $1.2 billion, and single-digit royalties on sales of products

that utilize the technology subject to the 2seventy Agreement. None of these events had occurred as of September 30, 2023, and no royalties were due from the sale of licensed products.

In August 2019, the Company entered into a First Amendment to the 2seventy Agreement, which extended the timeline for the Company and 2seventy to execute a Patient Selection Services Agreement from within one year to within two years after the effective date of the 2seventy Agreement. In August 2020, the Company entered into a Second Amendment, which extended the timeline of the Patient Selection Services Agreement to within three years and also extended the Tissue Analysis Period from February 28, 2021 to June 30, 2021. In April 2021, the Company entered into a Third Amendment, which removed the Patient Selection Services Agreement in its entirety and extended the Tissue Analysis Period from June 30, 2021 to December 31, 2021. The amendments were entered into for administrative purposes, and the Company determined the amendments were not a modification of contract under the contract with customers guidance.

2seventy may terminate the 2seventy Agreement by giving a 120-day prior written notice to the Company at any time after the effective date of the agreement. Unless terminated early, the agreement has a term that ends upon the last payment owed by the Company on a licensed product. The 2seventy Agreement may be terminated for cause by either party based on uncured material breach by the other party or bankruptcy of the other party. Upon early termination, all ongoing activities under the agreement and all mutual collaboration, development and commercialization licenses and sublicenses will terminate. The licenses granted by the Company to 2seventy under the licensed intellectual property will remain in effect in accordance with their respective terms. Additionally, all of 2seventy's payment obligations that have not yet accrued related to future milestone and royalty payments will be reduced by 50% for the remainder of the agreement term.

The Company concluded that 2seventy is a customer, and the contract is not subject to guidance on collaborative arrangements. This is because the Company granted to 2seventy a license to its intellectual property and provided research and development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration.

The Company identified the following three material promises under the 2seventy Agreement: (i) transfer of a license to intellectual property and related technology know-how ("License and Know-How"); (ii) the obligation to perform target selection and TCR generation services ("Research and Development Services"); and (iii) participation on the Joint Steering Committee (the "JSC"). The Company provided to 2seventy standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services.

The Company considered that the License and Know-How has standalone functionality, was considered to be functional intellectual property, and is capable of being distinct. However, the Company determined that the License and Know-How is not distinct from the Research and Development Services or participation on the JSC within the context of the 2seventy Agreement, because 2seventy is dependent on the Company to execute the Research and Development Services and participate on the JSC in order for 2seventy to benefit from the License and Know-How. As such, the License and Know-How is combined with the Research and Development Services and participation on the JSC into a single performance obligation, and the transaction price under this arrangement will be allocated to this single performance obligation.

The Company has also determined that all other goods or services that are contingent upon 2seventy reaching various milestones are not considered performance obligations at the inception of the arrangement.

The transaction price at the inception of the 2seventy Agreement consisted of the upfront payment of $20.0 million and the $10.0 million received from 2seventy for the purchase of the Company's Series C convertible preferred stock. The sale of the Series C convertible preferred stock was not considered to be a performance obligation, as it was a separate financing component of the transaction. Accordingly, $10.0 million of the transaction price was allocated to the issuance of 768,115 shares of Series C convertible preferred stock at fair value of $13.04 per share and recorded in stockholders' equity.

The variable consideration related to the remaining development, regulatory, and sales-based milestones payments has not been included in the initial transaction price and continues to be fully constrained as of September 30, 2023. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon initiation of clinical trials for early-stage targets and 2seventy's development efforts. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they were determined to relate predominantly to the

License and Know-How granted to 2seventy. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For revenue recognition purposes, the Company determined that the duration of the 2seventy Agreement began on the effective date in August 2018 and ends upon completion of the Research and Development Services, which is also when participation on the JSC is no longer an obligation. The contract duration is defined as the period in which parties to the contract have present enforceable rights and obligations. The Company also analyzed the impact of 2seventy terminating the agreement prior to August 2023 and determined, considering both quantitative and qualitative factors, that there were substantive non-monetary penalties to 2seventy for doing so.

Revenue is recognized when, or as, the Company satisfies its performance obligation by transferring the promised services to 2seventy. Revenue is being recognized over time using a cost-based input method, based on internal labor cost effort to perform the research services, since the internal labor cost incurred over time is thought to best reflect the transfer of services to 2seventy. In applying a cost-based input method of revenue recognition, we use actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. A cost-based input method of revenue recognition requires us to make estimates of costs to complete the performance obligation. The cumulative effect of any revisions to estimated costs to complete the performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

During the three and nine months ended September 30, 2023, the Company recognized $0.3 million and $1.0 million, respectively, and during the three and nine months ended September 30, 2022, the Company recognized $0.2 million and $6.5 million, respectively, in collaboration revenue under the 2seventy Agreement. The amount of collaboration revenue recognized during the nine months ended September 30, 2022 included cumulative catch-up adjustments increasing contribution revenue by $5.5 million due to revisions to estimated costs to complete the remaining performance obligation. The adjustments resulted in a decrease in the Company's loss from operations of $5.5 million and a decrease in loss per share of $0.06 for the nine months ended September 30, 2022. There is no deferred revenue recorded on the condensed consolidated balance sheet as of September 30, 2023. Deferred revenue of $1.0 million was recorded on the condensed consolidated balance sheet in current liabilities as of December 31, 2022. Deferred revenue relates to the performance obligations identified under the 2seventy Agreement that was recognized over the period the performance obligations were satisfied.

Changes in the deferred revenue balance during the nine months ended September 30, 2023 for the 2seventy Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2022	$ 1,047
Additions	—
Deductions	(1,047)
Balance at September 30, 2023	$ —

There were no receivables or net contract assets recorded as of September 30, 2023 and December 31, 2022 associated with the 2seventy Agreement.

Gilead Sciences, Inc.

In January 2021, the Company entered into a Collaboration, Option and License Agreement (the “Gilead Collaboration Agreement”) with Gilead Sciences, Inc. (“Gilead”) to research and develop a vaccine-based immunotherapy as part of Gilead’s efforts to find a curative treatment for HIV infection. Under the terms of the Gilead Collaboration Agreement, the Company granted to Gilead an exclusive, worldwide license to develop and commercialize a HIV-specific therapeutic vaccine utilizing the Company’s technology. Gilead is responsible for conducting all development and commercialization activities beginning with a Phase 1 study, and the Company is responsible for contributing to preclinical research studies and participation in a joint steering committee (collectively, “research and development activities”). Concurrently with execution of the Gilead Collaboration Agreement, the Company and Gilead entered into a Supply Agreement (the “Gilead Supply Agreement”) under which the Company will supply research product and GMP product (“Product Supply”) that may be required under the Gilead Collaboration Agreement until Gilead completes its first GMP product batch, and the Company will participate in a

joint manufacturing team (collectively, “product supply activities”). In addition, the Company also concurrently entered into a Stock Purchase Agreement (the “Gilead Stock Purchase Agreement”) under which Gilead acquired, in a private placement transaction, 1,169,591 shares of the Company’s common stock. The common shares were issued to Gilead with certain registration rights and certain standstill and market stand-off provisions. The Company determined that these concurrent contracts represent a combined arrangement (“the Gilead Arrangement”).

Under the Gilead Collaboration Agreement, the Company received a non-refundable upfront payment of $30.0 million. Under the Gilead Collaboration Agreement and the Gilead Supply Agreement, the Company will receive additional reimbursement payments for expenses incurred in the research and development activities and product supply activities. Under the Gilead Stock Purchase Agreement, the common shares were sold at a price of $25.65 per share for a total of $30.0 million. The Company’s common stock at fair value on closing was $18.10 per share. If Gilead decides to move forward with development beyond the initial Phase 1 study (the “Option”), the Company will receive a $40.0 million non-refundable option fee and will be eligible to receive up to an aggregate of $685.0 million if certain clinical, regulatory and commercial milestones are achieved, as well as tiered royalties ranging from the mid-single digits to low double-digits on net sales of a therapeutic product utilizing its technology. None of these events had occurred as of September 30, 2023 and no royalties were due from the sale of licensed products.

Gilead may terminate the Gilead Collaboration Agreement for convenience by giving a 90-day prior written notice to the Company at any time after the effective date of the agreement. Unless terminated early, the agreement has a term that ends upon the expiration of the royalty term, or, if the Option is not exercised, by the end of the Option term. The Gilead Collaboration Agreement may be terminated for cause by either party based on uncured material breach by the other party, insolvency of the other party, or patent challenge. Upon early termination, all ongoing activities under the agreement and all mutual collaboration, development and commercialization licenses and sublicenses will terminate. The licenses granted by the Company to Gilead under the licensed intellectual property will remain in effect in accordance with their respective terms. Additionally, if terminated early by Gilead for convenience or by the Company for material breach or insolvency, all of Gilead’s payment obligations for reimbursable costs or for future milestone and royalty payments remain. If terminated early by Gilead for material breach or insolvency, all of Gilead’s unaccrued payment obligations related to future milestone and royalty payments will be reduced by 50% for the remainder of the agreement term. Furthermore, Gilead may terminate the Gilead Supply Agreement without cause by giving six months prior written notice and any active orders with 60-day notice without terminating the agreement, and either party may terminate based on an uncured material breach, insolvency of the other party, or in the event that the Gilead Collaboration Agreement is terminated. Upon termination, the Company will deliver all supply products that have been produced and destroy, reimburse or deliver materials that Gilead has reimbursed, and Gilead must pay for any manufacturing costs that the Company has actually incurred or committed to pay, including any cancellation costs owed to subcontractors.

The Company concluded that Gilead is a customer and therefore revenue recognition should be accounted for in accordance with ASC 606, because the Company granted to Gilead licenses to its intellectual property and will provide research and development services and Supply of Product, as defined below, all of which are outputs of the Company’s ongoing activities, in exchange for consideration. The Option, if exercised by Gilead, will be considered a modification that increases the scope of the arrangement beyond the Option Term.

The Company identified the following performance obligations under the Gilead Collaboration Agreement: (i) licenses including an exclusive (in the HIV field), royalty-free, worldwide collaboration license and transfer of know-how and an exclusive (in the HIV field) worldwide, royalty-bearing development and commercial license subject to restrictions on its use during the Option Term and an exclusive option to release such restrictions; (ii) preclinical research and development activities, manufacturing-related activities, and participation on a Joint Steering Committee; and (iii) product supply, including research and GMP product, until Gilead completes its first GMP batch, and participation on a Joint Manufacturing Team.

The Company considered that the licenses and know-how have standalone functionality, are considered to be functional intellectual property and are capable of being distinct. The Company also determined that the research and development activities and product supply by Gritstone could be provided by resources otherwise available to Gilead and thus are capable of being distinct.

The Company has also determined that the pricing for optional goods and services and release of license restrictions upon exercise of the Option do not constitute material rights and are not a potential performance obligation. The Company evaluated whether there is an interdependence between the promises and determined that the licenses are a combined solution and the predominant performance obligation, while the other promises are separately

identifiable in the context of the contract; however, the research and development activities are dependent on the research product supply, which is accounted for as a combined performance obligation. As a result, the Company identified three performance obligations in the Gilead Arrangement: (i) exclusive licenses and know-how, (ii) research and development activities and product supply, and (iii) GMP product supply.

The transaction price at the inception of the Gilead Collaboration Agreement consisted of the upfront payment of $30.0 million and the $30.0 million received for the sale of the Company's common stock. The sale of the common stock was not considered to be a performance obligation, as it was a separate financing component of the transaction. Accordingly, $21.2 million of the transaction price was allocated to the issuance of 1,169,591 shares of the Company's common stock at fair value on closing of $18.10 per share and recorded in stockholders' equity. The remaining $8.8 million of the common stock purchase price in excess of the fair value of the shares received is added to the transaction price for the Gilead Collaboration Agreement. In addition, the initial transaction price includes estimated variable consideration for budgeted reimbursement of research and development costs and product supply. The variable consideration related to reimbursable costs and product supply has been constrained as of September 30, 2023 based on the current research and development plan forecast. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that the variable consideration for the $40.0 million option exercise fee and for the development, regulatory, and sales-based milestones payments were probable of significant revenue reversal as their achievement was highly dependent on factors outside the Company's control. As a result, these payments were fully constrained and were not included in the transaction price. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they were determined to relate predominantly to the exclusive licenses and know-how granted to Gilead.

The transaction price is allocated to the performance obligation based upon relative standalone selling prices, which were determined for the exclusive licenses and know-how using an adjusted market approach and for the research and development activities and product supply using a cost plus reasonable margin approach. Variable consideration is allocated to the specific performance obligations to which it relates.

For revenue recognition purposes, the Company determined that the duration of the contract began on the effective date in January 2021 and ends upon (i) the completion of the Option term, which is expected to end within four years after the effective date, if the Option is not exercised or (ii) the expiration of the royalty-term on a product-by-product and country-by-country basis. The Company also analyzed the impact of Gilead terminating the agreement prior to the end of the Option term and determined, considering both quantitative and qualitative factors, that there were substantive non-monetary penalties to Gilead for doing so.

Revenue for the exclusive licenses and know-how was recognized on the effective date of the Gilead Collaboration Agreement at the point in time that the licenses are effective. The research and development activities and product combined performance obligation and the GMP product supply performance obligation are recognized over time when, or as, the Company transfers the promised goods and services to Gilead. Research and development service and product supply revenues will be recognized over time using a cost-based input method, based on internal and external labor cost effort to perform the services, costs to acquire research materials, and costs of product supply, since the costs incurred over time are thought to best reflect the transfer of goods and services to Gilead. In applying a cost-based input method of revenue recognition, we use actual costs incurred relative to estimated total costs to fulfill each performance obligation. A cost-based input method of revenue recognition requires us to make estimates of costs to complete the performance obligation. The cumulative effect of any revisions to estimated costs to complete the performance obligation and associated variable consideration will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

For the three and nine months ended September 30, 2023, the Company did not record any license revenue and recorded $0.1 million and $0.3 million, respectively, as collaboration revenue as a result of satisfying its performance obligations by transferring the promised goods and services for the Gilead Collaboration Agreement. For the three and nine months ended September 30, 2022, the Company did not record any license revenue and recorded $0.2 million and $1.5 million, respectively, as collaboration revenue as a result of satisfying its performance obligations by transferring the promised goods and services for the Gilead Collaboration Agreement. There was no contract asset recorded on the condensed consolidated balance sheets as of September 30, 2023 or December 31, 2022.

There was $0.1 million recorded as deferred revenue as of September 30, 2023 and December 31, 2022 associated with the Gilead Collaboration Agreement.

Changes in the deferred revenue balance during the nine months ended September 30, 2023 for the Gilead Collaboration Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2022	$ 107
Additions	—
Deductions	(40)
Balance at September 30, 2023	$ 67

There was $0.1 million of receivables recorded on the condensed consolidated balance sheets as a current asset in the prepaid expenses and other current assets balance as of September 30, 2023 and December 31, 2022, associated with the Gilead Collaboration Agreement.

The Company deferred $0.1 million in incremental costs to acquire the Gilead Collaboration Agreement in the first quarter of 2021 allocated to performance obligations recognized over time, which will be recognized over time in each period proportionate to revenue recognition. There were no deferred contract acquisition costs amortized during the three and nine months ended September 30, 2023 as they were fully amortized during the year ended December 31, 2022. Deferred contract acquisition costs amortized during the three and nine months ended September 30, 2022 were negligible.

Arbutus Biopharma Corporation

In October 2017, the Company entered into an Exclusive License Agreement with Arbutus and its wholly-owned subsidiary, Protiva Biotherapeutics Inc. Certain terms of the agreement were modified by amendment in July 2018. Under the license agreement, the Company has an exclusive license to utilize certain Arbutus intellectual property, including patents and know-how relating to immunotherapy. During the three and nine months ended September 30, 2023 and 2022, the Company had no research and development expense under the agreement. The Company is obligated to pay Arbutus certain milestone payments up to $123.5 million on achievement of specified events, and royalties on sales of its licensed products. Following the acceptance of our investigational new drug application for GRANITE by the FDA, the Company made a $2.5 million development milestone payment to Arbutus in September 2018 that was recorded as research and development expense. In August 2019, a milestone was met following the initial patient treatment of SLATE in the Company's GO-005 clinical trial. In 2019, the Company recorded $3.0 million as research and development expense in connection with the milestone. None of the other events had occurred as of September 30, 2023, and no royalties were due from the sale of licensed products.

Non-Profit Hospital Cancer Center

In January 2016, the Company entered into an Exclusive License Agreement with a non-profit hospital cancer center. Under the license agreement, the Company has an exclusive license to utilize certain patents and know-how relating to immunotherapy for an insignificant upfront payment, cash milestone payments on achievement of specified events, and low single digit royalties on sales of licensed products. The achievement of the milestones and payment of royalties is dependent upon obtaining regulatory approval. Upon achievement of a milestone related to the Company's Phase 1 clinical trial for GRANITE, GO-004, in December 2018 the Company recorded an insignificant amount to research and development expense for amounts owed to the Hospital Cancer Center, which was paid to the hospital in February 2019. None of the other milestone events had occurred as of September 30, 2023 and no royalties were due from the sales of licensed products.

Genevant Sciences GmbH

In October 2020, the Company entered into an Option and License and Development Agreement (as amended, the "2020 Genevant License Agreement") with Genevant Sciences GmbH ("Genevant"), pursuant to which Genevant granted the Company exclusive license rights under certain intellectual property related to Genevant's LNP technology for a single therapeutic indication, and the Company agreed to pay Genevant an initial payment of $2.0 million, up to an aggregate of $71.0 million in specified development, regulatory, and commercial milestones, and low to mid-single digit royalties on net sales of licensed products. The upfront payment of $2.0 million was included in research and

development expense for the year ended December 31, 2020. Genevant is a spin-off of Arbutus, and the 2020 Genevant License Agreement expands Gritstone's intellectual property rights to such LNP technology originally obtained pursuant to the Company's license agreement with Arbutus. Prior to the 2020 Genevant License Agreement, the Company licensed Arbutus' LNP technology for indications in the oncology space. The remainder of Arbutus' IP portfolio was transferred to Genevant in the spin-off. In March 2022, a milestone in the amount of $1.0 million was met, which was included in research and development expense for the year ended December 31, 2022.

Pursuant to the 2020 Genevant License Agreement, Genevant also granted the Company certain options to license the LNP technology for additional indications of up to $1.5 million for each indication and $1.0 million to extend the option term. The 2020 Genevant License Agreement continues in effect until the last to expire royalty term or early termination. It is terminable by the Company for convenience with 90 days prior written notice or immediately if based on certain product safety or efficacy or regulatory criteria. Either party may terminate the agreement for material breach, subject to a cure period, and Genevant may terminate the agreement if the Company challenges a licensed patent.

In January 2021, the Company entered into a Non-Exclusive License and Development Agreement (the "2021 Genevant License Agreement") with Genevant. Pursuant to the 2021 Genevant License Agreement, the Company obtained a nonexclusive license to Genevant's LNP technology to develop and commercialize self-amplifying RNA ("samRNA") vaccines against SARS-CoV-2, the virus that causes COVID-19. Under the 2021 Genevant License Agreement, the Company made a $1.5 million upfront payment to Genevant, and Genevant is eligible to receive from the Company up to an aggregate of $191.0 million in contingent milestone payments per product, plus certain tiered royalties, upon achievement of development and commercial milestones. In certain scenarios, in lieu of milestones and royalties, Genevant will be entitled to a percentage of amounts that the Company receives from sublicenses under the 2021 Genevant License Agreement, subject to certain conditions. In March 2021, a milestone in the amount of $1.0 million was met following the initial patient treatment in the Phase 1 clinical trial conducted through the NIAID-supported Infectious Diseases Clinical Research Consortium ("IDCRC"). Both the $1.5 million upfront and $1.0 million milestone payments were recorded as research and development expense for the year ended December 31, 2021. None of the other milestone events had occurred as of September 30, 2023.

In August 2023, the Company entered into an Option and Non-Exclusive License and Development Agreement (the "2023 Genevant License Agreement") with Genevant. Pursuant to the 2023 Genevant License Agreement, the Company obtained a multi-year option for a non-exclusive license under Genevant's LNP technology on a pathogen-by-pathogen basis to develop and commercialize samRNA vaccines against infectious disease. Under the 2023 Genevant License Agreement, (i) the Company made a $2.5 million upfront payment to Genevant, recorded as research and development expense for the three and nine months ended September 30, 2023, and (ii) Genevant is eligible to receive from the Company option maintenance and exercise fees in the single digit millions and up to an aggregate of $136.0 million in contingent milestone payments per product, subject to increase for multi-pathogen products and in other specified circumstances, and royalties ranging from the mid to high single digits on future product sales. If Gritstone outlicenses an applicable infectious disease program, in lieu of certain of these payments, Genevant may be entitled to a percentage of amounts that Gritstone receives from its sublicensee. None of the milestone events under the 2023 Genevant License Agreement had occurred as of September 30, 2023.

In August 2023, the 2020 Genevant License Agreement was amended to terminate the options to license the LNP technology for additional indications.

Coalition for Epidemic Preparedness Innovations

On August 14, 2021, the Company entered into the CEPI Funding Agreement with CEPI, under which CEPI agreed to provide funding of up to $20.6 million to the Company to advance the Company's program, which is developing a second-generation COVID-19 vaccine, with an initial clinical trial in South Africa. Under the terms of the agreement, CEPI will fund a multi-arm Phase 1 study evaluating the CORAL program's samRNA vaccine in naïve, convalescent, and HIV+ patients. The study will evaluate three different samRNA vaccine constructs that each target both the spike protein and other SARS-CoV-2 targets and are designed to drive both robust B and T cell immune responses. The funding will also support pre-clinical studies, scale-up and formulation development to enable manufacturing of large quantities of stable vaccine product.

Under the terms of the CEPI Funding Agreement, among other things, the Company and CEPI agreed on the importance of global equitable access to the vaccine produced pursuant to the CEPI Funding Agreement. The vaccine, if approved, is expected to be made available to the COVAX Facility for procurement and allocation. The COVAX

Facility aims to deliver equitable access to COVID-19 vaccines for all countries, at all levels of development, that wish to participate.

The scope and continuation of the CEPI Funding Agreement may be amended depending on ongoing developments of the COVID-19 outbreak and the success of the Company's COVID-19 vaccine candidate developed under the CEPI Funding Agreement relative to other third-party COVID-19 vaccine candidates or treatments. If the World Health Organization (WHO), CEPI or a regulatory authority having jurisdiction over a clinical trial performed under the CEPI Funding Agreement determines that a third-party product candidate has substantially greater potential than the Company's COVID-19 vaccine candidate developed under the CEPI Funding Agreement and should be prioritized instead for a particular trial, the Company must consider in good faith any written request of CEPI not to proceed with a clinical trial of such COVID-19 vaccine candidate (the determination of whether to proceed or not with such trial shall be made by the Company in its sole discretion). In addition, CEPI has the right to unilaterally terminate the CEPI Funding Agreement upon prior written notice if CEPI determines that (i) there are material safety, regulatory, scientific misconduct or ethical issues with the project undertaken by the Company under the CEPI Funding Agreement, (ii) the project undertaken by the Company under the CEPI Funding Agreement should be terminated, (iii) the Company becomes unable to discharge its obligations under the CEPI Funding Agreement, (iv) the Company fails to meet certain criteria set forth in the CEPI Funding Agreement, or (v) the Company commits fraud or a financial irregularity, as such terms are defined in the CEPI Funding Agreement.

In December 2021, the Company and CEPI entered into an amendment to the CEPI Funding Agreement, under which CEPI agreed to provide additional funding of up to $5.0 million, for a total of up to $25.6 million, to the Company to conduct a Phase I clinical trial of the Company's Omicron vaccine candidate in South Africa.

CEPI advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the CEPI Funding Agreement. The first tranche of funding of $11.3 million was received in September 2021, the second tranche of funding of $2.7 million was received in April 2022 and the third tranche of funding of $1.2 million was received in June 2023.

Payments received in advance that are related to future performance are deferred and recognized as grant revenue when the research and development activities are performed. Cash payments received under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. The Company recognized grant revenue of $0.9 million and $3.4 million, respectively, during the three and nine months ended September 30, 2023, and $2.3 million and $6.9 million, respectively, during the three and nine months ended September 30, 2022 under the CEPI Funding Agreement. As of September 30, 2023 and December 31, 2022, short-term deferred revenue of $0.8 million and $3.0 million, respectively, was recorded on the condensed consolidated balance sheets. Deferred revenue will be recognized over the period in which the funding agreement activities related to the tranches of funding are expected to take place, which is currently estimated to be through the end of the year 2023. As of September 30, 2023 and December 31, 2022, $0.8 million and $3.0 million, respectively, was recorded as short-term restricted cash on the condensed consolidated balance sheet.

Changes in the deferred revenue balance during the nine months ended September 30, 2023 for the CEPI Funding Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2022	$ 2,952
Additions	1,215
Deductions	(3,359)
Balance at September 30, 2023	$ 808

Gates Foundation

In November 2021, the Company entered into a Grant Agreement with the Gates Foundation ("Gates Grant Agreement"), under which the Company will develop an optimal immunogen in the context of a therapeutic human papillomavirus ("HPV") vaccine. In consideration for the work to be performed, the Gates Foundation provided the Company with an upfront payment of $2.2 million in December 2021, and an additional $0.7 million was received in April 2023.

Payments received in advance that are related to future performance are deferred and recognized as grant revenue when the research and development activities are performed. Cash payments received under the Gates Grant

Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. The Company did not recognize any grant revenue under the Gates Grant Agreement in 2021. The Company recognized grant revenue of $0.4 million and $1.3 million, respectively, during the three and nine months ended September 30, 2023, and $0.3 million and $0.8 million, respectively, during the three and nine months ended September 30, 2022 under the Gates Grant Agreement. As of September 30, 2023 and December 31, 2022, short-term deferred revenue of $0.4 million and $1.0 million, respectively, was recorded on the condensed consolidated balance sheets. Deferred revenue will be recognized over the period in which the funding agreement activities related to the tranches of funding are expected to take place, which is currently estimated to be through the year ended 2023.

Changes in the deferred revenue balance during the nine months ended September 30, 2023 for the Gates Grant Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2022	$ 1,025
Additions	700
Deductions	(1,299)
Balance at September 30, 2023	$ 426

Biomedical Advanced Research and Development Authority

In September 2023, the Company entered into a contract (the “BARDA Contract”) with the Biomedical Advanced Research and Development Authority, part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services ("BARDA"). Under the BARDA Contract, the Company may be eligible to receive funding of up to an estimated $433.0 million to conduct a 10,000-participant randomized Phase 2b comparative study evaluating the Company’s next-generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The BARDA Contract could result in payments to the Company of up to approximately $433.0 million. The BARDA Contract consists of a base period (ending on or before the first quarter of 2024) and a total contract period-of-performance (base period plus two stages gated at BARDA’s discretion) of up to approximately four years. The base period for the BARDA Contract includes government funding of up to approximately $10.0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. Following successful completion of the base period, the BARDA Contract provides for up to approximately $423.0 million of additional BARDA funding for two stages gated at BARDA’s discretion in support of the clinical trial execution and additional analyses for the clinical trial. The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

The Company did not recognize any revenue under the BARDA Contract for the three and nine months ended September 30, 2023. No amounts have been received under the BARDA Contract as of September 30, 2023

10. Stockholders’ Equity

The Company’s amended and restated certificate of incorporation, as amended provides for 300,000,000 shares of common stock and 10,000,000 shares of preferred stock authorized for issuance, each with a par value of $0.0001 per share.

As of September 30, 2023 and December 31, 2022, no shares of preferred stock were issued and outstanding.

As of September 30, 2023 and December 31, 2022, there were 93,075,427 and 86,894,901 shares of common stock issued and outstanding, respectively. Holders of the Company’s common stock are entitled to one vote per share.

Sale of Common Stock and Pre-Funded Warrants

In December 2020, the Company entered into two private placement financing transactions (collectively, the “First PIPE Financing”), as follows: (i) to sell 5,543,351 shares of its common stock at a price of $3.34 per share and pre-funded warrants (the “Warrants”) to purchase 27,480,719 shares of common stock at a price of $3.34 per share (of which $3.33 per share was prepaid by each purchaser), and (ii) to sell an additional 4,043,127 shares of its common stock at a price per share of $3.71. In connection with the First PIPE Financing, the Company received aggregate net

proceeds of approximately $119.8 million. The Warrants are exercisable upon issuance at an exercise price of $0.01 per share.

The outstanding Warrants generally may not be exercised if the holder's aggregate beneficial ownership would be more than 9.99% of the total issued and outstanding shares of the Company's common stock following such exercise. The exercise price and number of shares of common stock issuable upon the exercise of the Warrants (the "Warrant Shares") are subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrant agreements. Under certain circumstances, the Warrants may be exercisable on a "cashless" basis. In connection with the issuance and sale of the common stock and Warrants, the Company granted the purchasers certain registration rights with respect to the Warrants and the Warrant Shares.

The Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Warrants do not provide any guarantee of value or return. The Company valued the Warrants at issuance, concluding their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and Warrants, of which $87.7 million, net of issuance costs, was allocated to the Warrants and recorded as a component of additional paid-in-capital.

In September 2021, the Company completed a PIPE financing transaction, in which it sold 5,000,000 shares of its common stock at a price of $11.00 per share pursuant to a securities purchase agreement entered into on September 16, 2021 (the "Second PIPE Financing"). The Company received aggregate net proceeds of approximately $52.7 million after deducting placement agent commissions and offering expenses payable by the Company. In connection with the issuance and sale of the common stock, the Company agreed to file a registration statement with the SEC registering the resale of the shares of common stock issued in the Second PIPE Financing.

In March 2022, the Company filed a Registration Statement on Form S-3 with the SEC (the "2022 Shelf Registration Statement"), covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. The 2022 Shelf Registration Statement included a prospectus supplement covering the issuance and sale of up to $100.0 million of the Company's common stock, from time to time, through an "at-the-market" offering program (the "2022 ATM Offering Program") under the Securities Act. The SEC declared the 2022 Shelf Registration Statement effective as of May 6, 2022.

In connection with the 2022 ATM Offering Program, in March 2022, the Company also entered into a sales agreement (the "2022 Sales Agreement") with Cowen, pursuant to which Cowen will act as the Company's sales agent and, from time to time, offer and sell shares of the Company's common stock having an aggregate offering price of up to $100.0 million. Cowen is entitled to compensation for its services equal to up to 3.0% of the gross proceeds of any shares of common stock sold under the 2022 Sales Agreement. In addition, the Company agreed to reimburse a portion of Cowen's expenses in connection with the 2022 ATM Offering Program up to $50,000. As of December 31, 2022, the Company has received aggregate proceeds from its 2022 ATM Offering Program of $19.6 million, net of commissions and offering costs, pursuant to the issuance of 7,034,948 shares of its common stock. As of September 30, 2023, the Company has received aggregate proceeds from its 2022 ATM Offering Program of $22.1 million, net of commissions and offering costs, pursuant to the issuance of 7,889,000 shares of its common stock.

In October 2022, the Company completed a PIPE financing transaction, in which it sold 6,637,165 shares of its common stock at a price of $2.26 per share pursuant to a securities purchase agreement entered into on October 24, 2022 and pre-funded warrants (the "Warrants") to purchase 13,274,923 shares of common stock at a price of $2.26 per share (of which $2.2599 per share was prepaid by each purchaser) (the "Third PIPE Financing"). The Company received aggregate net proceeds of approximately $42.4 million after deducting placement agent commissions and offering expenses payable by the Company. In connection with the issuance and sale of the common stock, the Company agreed to file a registration statement with the SEC registering the resale of the shares of common stock issued in the Third PIPE Financing. The Warrants are exercisable upon issuance at an exercise price of $0.0001 per share.

The outstanding Warrants generally may not be exercised if the holder's aggregate beneficial ownership would be more than 9.99% of the total issued and outstanding shares of the Company's common stock following such exercise. The exercise price and number of shares of common stock issuable upon the exercise of the Warrants (the "Warrant Shares") are subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrant agreements. Under certain circumstances, the Warrants may be exercisable on a "cashless" basis. In connection with the issuance and sale of the common stock and Warrants, the Company granted the purchasers certain registration rights with respect to the Warrants and the Warrant Shares.

The Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Warrants do not provide any guarantee of value or return. The Company valued the Warrants at issuance, concluding their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and Warrants, of which $28.2 million, net of issuance costs, was allocated to the Warrants and recorded as a component of additional paid-in-capital.

Common Stock Warrants

As of September 30, 2023, the following warrants to purchase shares of the Company's common stock were issued and outstanding:

Issue Date	Expiration Date	Exercise Price	Number of Warrants Outstanding
December 28, 2020	None	$ 0.01	9,064,833
October 24, 2022	None	$ 0.0001	13,274,923
			22,339,756

There were 1,648,900 and 4,508,871 warrants exercised during the three and nine months ended September 30, 2023, respectively, resulting in the Company issuing 4,498,305 shares of common stock due to net exercise of some of the warrants. During the nine months ended September 30, 2022, 3,442,567 warrants were exercised resulting in the Company issuing 3,442,567 shares of common stock.

11. Stock-Based Compensation

Award Incentive Plans

In August 2015, the Company's board of directors approved the 2015 Equity Incentive Plan ("2015 Plan"). In connection with the Company's IPO and the effectiveness of the 2018 Award Incentive Plan ("2018 Plan"), discussed below, the 2015 Plan terminated. The 92,815 shares of common stock that were then unissued and available for future issuance under the 2015 Plan became available under the 2018 Plan.

In September 2018, the Company's board of directors approved the 2018 Plan. Under the 2018 Plan, a total of 2,690,000 shares of common stock were initially reserved for issuance under the 2018 Plan, plus the number of shares remaining available for future awards under the 2015 Plan, as of the effective date of the 2018 Plan. The number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, by 4% of the total number of shares of the Company's outstanding stock on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The 2018 Plan provides, among others, for the grant of options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance bonus awards.

The maximum number of shares that may be issued upon the exercise of stock options under the 2018 Plan is 45,000,000.

The Company's board of directors has the authority to determine to whom options will be granted, the number of shares, the term, and the exercise price. If an individual owns stock representing 10% or more of the outstanding shares, the price of each share shall be at least 110% of the fair market value, as determined by the board of directors. Options granted have a term of up to 10 years and generally vest over a 4-year period with a straight-line vesting.

Material Features of the 2021 Employment Inducement Incentive Award Plan

In April 2021, the Company's board of directors adopted the 2021 Employment Inducement Incentive Award Plan (the "2021 Plan"), pursuant to Nasdaq Listing Rule 5635(c)(4). The principal purpose of the 2021 Plan is to enhance our ability to attract, retain and motivate employees who are expected to make important contributions to us by providing such individuals with equity ownership opportunities. Awards granted under the 2021 Plan are intended to constitute "employment inducement awards" under Nasdaq Listing Rule 5635(c)(4), and, as such, the 2021 Plan is intended to be exempt from the Nasdaq Listing Rules regarding shareholder approval of stock option and stock purchase plans. A total of 790,400 shares of our common stock ("Share Limit") were initially reserved for issuance under the 2021 Plan. The Share Limit may be increased by the Company's board of directors. The 2021 Plan provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, stock appreciation rights, and other stock-based and cash-based awards. The 2021 Plan does not provide for the grant of incentive stock options. Awards under the 2021 Plan may be granted to eligible employees who are either new employees or who are commencing employment with the Company or one of its subsidiaries following a bona fide period of non-employment with the Company, and for whom such awards are granted as a material inducement to commencing employment with the Company or one of its subsidiaries. Awards under the 2021 Plan may not be granted to the Company's consultants or non-employee directors.

The 2021 Plan is administered by our board of directors and the Company's compensation committee, acting pursuant to the delegation by our board of directors. In the event of a change in control in which the Company's successor refuses to assume or substitute any outstanding award under the 2021 Plan, the vesting of such award will accelerate in full. The Company's board of directors may terminate, amend, or modify the 2021 Plan at any time, provided that no termination or amendment may materially impair any rights under any outstanding award under the 2021 Plan without the consent of the holder.

On April 21, 2022, the Company's board of directors increased the number of shares available under the 2021 Plan by 700,000 shares. On February 2, 2023, the Company's board of directors increased the number of shares available under the 2021 Plan by 1,300,000 shares.

Stock Option Activity

A summary of the 2018 Plan and 2021 Plan activity is as follows:

		Options Outstanding			
	Number of Shares Available for Issuance	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2022	4,814,394	6,951,620	$ 7.92	8.08	$ 1,089
Authorized	4,775,796	—	$ —		
Granted	(4,123,753)	608,966	$ 2.25		
Exercised	—	(6,000)	$ 0.76		
Canceled	704,071	(289,043)	$ 5.29		
Balance at September 30, 2023	6,170,508	7,265,543	$ 7.55	7.49	$ 141
Vested and exercisable at September 30, 2023		4,353,806	$ 8.58	6.85	$ 140
Vested and expected to vest at September 30, 2023		6,934,041	$ 7.65	7.44	$ 141

For the nine months ended September 30, 2023 and 2022, the total intrinsic value of stock option awards exercised was less than $0.1 million and $0.4

million, respectively, determined at the date of option exercise, and the total cash received upon exercise of stock options was not significant for either period. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying stock option awards and the estimated fair value of the common stock on the date of exercise.

As of September 30, 2023, $10.0 million of total unrecognized compensation cost related to non-vested employee and consultant options is expected to be recognized over a weighted-average period of 1.83 years. The total fair value of shares vested during the nine months ended September 30, 2023 was $6.1 million.

Stock-based compensation expense and awards granted to non-employees were $0.6 million and $0.5 million, respectively, for the nine months ended September 30, 2023 and 2022.

Restricted Stock Units

The Company has granted restricted stock unit awards under the 2018 Equity Plan. The restricted stock unit awards have a term of up to 10 years and generally vest over a 6 month, 1 or 2-year period. The following table summarizes the Company's restricted stock unit activity during the nine months ended September 30, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding, unvested at December 31, 2022	561,526	$ 5.38
Issued	3,514,787	$ 3.29
Vested	(871,385)	$ 4.64
Canceled/Forfeited	(91,623)	$ 3.29
Outstanding, unvested at September 30, 2023	3,113,305	$ 3.29

Stock-Based Compensation Expense

Total stock-based compensation for all awards granted to employees, consultants and the Company's 2018 Employee Stock Purchase Plan (“ESPP”), before taxes, is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expenses	$ 1,565	$ 1,615	$ 4,809	$ 5,083
General and administrative expenses	1,399	1,449	3,986	4,466
Total	$ 2,964	$ 3,064	$ 8,795	$ 9,549

12. Net Loss Per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents.

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except for share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (38,434)	$ (29,966)	$ (107,672)	$ (88,397)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	115,342,613	86,597,405	114,898,379	86,441,212
Net loss per share, basic and diluted	$ (0.33)	$ (0.35)	$ (0.94)	$ (1.02)

In December 2020, the Company issued and sold the 2020 Warrants to purchase 27,480,719 shares of common stock at a nominal exercise price of $0.01 per share

and, in October 2022, the Company issued and sold the 2022 Warrants to purchase 13,274,923 shares of common stock at a nominal exercise price of $0.0001 per share (see Note 10). The shares of common stock into which the 2020 and 2022 Warrants may be exercised are considered outstanding for the purposes of computing earnings per share, because the shares may be issued for little or no consideration, they are fully vested and the Warrants are immediately exercisable upon their issuance date.

During a period of net loss, basic net loss per share is the same as diluted net loss per share, as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	September 30,	
	2023	2022
Options issued and outstanding and ESPP shares issuable and outstanding	7,516,541	7,117,085
Restricted stock subject to future vesting	3,113,305	563,045
Total	10,629,846	7,680,130

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

You should read the following discussion and analysis of our financial condition and results of operations together with the condensed consolidated financial statements and notes thereto included elsewhere in this report, and our audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2022. This discussion and analysis, and other parts of this report, contain forward-looking statements, including, but not limited to, our clinical and regulatory development plans for our product candidates; our expectations regarding the data to be derived in our ongoing and planned clinical trials; the timing of commencement of our future nonclinical studies, clinical trials and research and development programs; our ability to discover, develop and advance product candidates into, and successfully complete, clinical trials; our plans and strategy regarding maintaining existing and entering into new collaborations and/or partnerships; the timing or likelihood of regulatory filings and approvals for our product candidates; our expectations regarding the impact of the COVID-19 pandemic or the end of the COVID-19 pandemic on our operations; and the sufficiency of our capital resources. These forward-looking statements are identified by their use of terms and phrases, such as "believe," "could," "aim," "expect," "intend," "may," "plan," "will," and other similar terms and phrases, including references to assumptions. Such forward-looking statements involve substantial risks and uncertainties that could cause the outcome of Gritstone's programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements, including that interim results obtained may differ from those at completion of the studies and clinical trials. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including our programs' clinical development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, our ability to successfully establish, protect and defend its intellectual property and other matters that could affect the sufficiency of existing cash to fund our operations. Our actual results could differ materially from those discussed in these forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to our business in general, see the section titled "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2022 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason.

Overview

We are a clinical-stage biotechnology company that aims to develop the world's most potent vaccines. Specifically, we discover, develop, manufacture and deliver vaccine-based immunotherapy candidates against cancer and infectious disease. Our goal is to unlock more potent and durable immunity by harnessing vaccine innovation. We aim to achieve that goal by leveraging our in-house capabilities and technologies to address the shortcomings of currently available vaccines and immunotherapies.

The immune system sits at the nexus of many diseases, and we believe that immune response modulation is core to several transformational product classes. Recent advances have pointed to T cells as being central to the success of cancer immunotherapy and critical in the elimination of virally infected cells. We believe that our scientific approach of focusing on generating antigen-specific T cells, particularly the challenging but critical cytotoxic CD8+ T cell subclass, has the potential to drive transformational therapeutic and prophylactic benefits.

In oncology, we develop personalized vaccines that aim to destroy tumors through CD8+ (killer) T cell recognition of tumor cells by virtue of their surface display of neoantigens, peptides that are presented on cancer cells when certain mutations occur in tumor DNA. In infectious disease, we develop both therapeutic and prophylactic vaccines targeting both T cells and B cells. We believe we are leading the field of development and application of self-amplifying mRNA (samRNA), a rapidly emerging platform technology. Our unique approach to immunogen design, whereby our vaccines deliver, as appropriate, whole proteins to drive neutralizing antibodies (nAbs) and/or protein fragments to drive T cell responses, has the potential to both neutralize incoming pathogens (through nAbs) and kill infected cells through CD8+ T cell recognition of foreign, pathogen-derived peptides displayed on the surface of infected cells.

Our clinical programs include GRANITE, an individualized neoantigen-based vaccine program; SLATE, an "off-the-shelf" neoantigen-based vaccine program; CORAL, a next-generation SARS-CoV-2 vaccine program; and HIV, an HIV vaccine program in collaboration with Gilead Sciences, Inc (Gilead).

The table below summarizes key information about our active and recently completed clinical trials.

Program	Phase	Status	Indication(s)	Collaborator	Commercial Rights
GRANITE	2/3	Enrollment Completed (Ph2 portion); Treatment Ongoing	MSS-CRC* first line maintenance	—	Gritstone
GRANITE	1/2	Completed	Early stage & advanced solid tumors	—	Gritstone
SLATE	1/2	Completed	KRAS advanced solid tumors	—	Gritstone
SLATE	1	IND Cleared	Mutant KRAS solid tumors	NCI	Gritstone***
CORAL	1	Active, not recruiting	SARS-CoV-2 in South Africa	CEPI	Gritstone
CORAL	1	Completed	SARS-CoV-2 booster	—	Gritstone
CORAL	1	Completed	SARS-CoV-2 naïve & booster	NIAID, IDCRC	Gritstone
HIV	1	Ongoing	HIV treatment/cure	Gilead Sciences	Gilead**

* MSS-CRC = microsatellite stable colorectal cancer
** Gilead is responsible for conducting a Phase 1 study
*** National Cancer Institute (NCI) is responsible for conducting a Phase 1 study.

Beyond GRANITE, SLATE, CORAL and the HIV collaboration with Gilead, we continue to apply our broad set of capabilities in oncology and infectious diseases through promising preclinical work and partnerships.

Impact of the COVID-19 pandemic on our Business

Although our operations have not been materially impacted by the COVID-19 pandemic, we have experienced slowing of patient recruitment and sample collection in our ongoing clinical trials. To date, the COVID-19 pandemic has not materially affected our supply chain or production schedule, but further escalation of the health crisis has the potential to cause delays in our supply chain and manufacturing operations, which could materially adversely impact our business.

We note that on May 11, 2023, the COVID-19 Public Health Emergency declared by the U.S. Department of Health and Human Services, declared under Section 319 of the Public Health Service Act, expired. Previously, on May 4, 2023, the WHO Director-General determined that COVD-19 is now an established and ongoing health issue which no longer constitutes a public health emergency of international concern. We continue to monitor what, if any, impact these developments may have on our business, financial condition, results of operations or prospects.

Oncology Program Updates

We are developing a portfolio of vaccine-based cancer immunotherapy product candidates using a heterologous prime (ChAd)/boost (samRNA) approach aimed at the highly targeted activation of tumor-specific neoantigens (TSNA) in solid tumors. Our two clinical-stage programs (GRANITE, which is "individualized" and SLATE, which is "off-the-shelf") aim to induce a substantial neoantigen-specific CD8+ T cell response using neoantigen-containing immunotherapies. GRANITE patients receive a product candidate made specifically for them, based upon their tumor DNA/RNA sequence. In contrast, SLATE patients receive an off-the-shelf product candidate made for a subset of patients based on common driver mutations.

GRANITE – Individualized Vaccine Program for Solid Tumors

Our first oncology program, GRANITE, consists of individualized neoantigen-based immunotherapy candidates for solid tumors. GRANITE was granted Fast Track designation by the FDA for the treatment of microsatellite stable colorectal cancer (MSS-CRC) in 2018.

Data generated from our Phase 1/2 study evaluating GRANITE in combination with checkpoint inhibitors in 3rd line MSS-CRC and other advanced solid tumors demonstrated positive results. Among all cohorts (n=29), the vaccine regimen was shown to be generally well-tolerated with no dose limiting toxicities and demonstrated consistent and potent CD8+ neoantigen-specific T cell induction. Additionally, an association between molecular responses (as

measured by a >30% reduction from baseline in circulating tumor DNA, ctDNA) and improved clinical outcomes (including overall survival) was observed in patients with MSS-CRC.

As of August 31, 2022, 55% of patients within the MSS-CRC cohort (n=13) demonstrated a molecular response (6/11 evaluable patients). Among molecular responders (n=6), the median overall survival (mOS) had not yet been reached and was expected to exceed at least 22 months. This compares to mOS of 7.8 months in evaluable MSS-CRC patients who did not exhibit a molecular response in the study, and a mOS of 6-7 months for patients who receive standard of care in phase 3 trials (Trifluridine/tipiracil combo and Regorafenib monotherapy). Interim results from the Phase 1/2 study of GRANITE were published in Nature Medicine in August 2022.

Upon assessing initial results of the GRANITE Phase 1/2 study, we discussed potential registrational paths with the FDA and subsequently initiated a randomized, controlled Phase 2/3 trial in newly diagnosed metastatic CRC patients that has registrational intent (NCT05141721). The study, which is evaluating GRANITE as a maintenance treatment in patients with first-line MSS-CRC who have completed FOLFOX (or FOLFOXIRI)-bevacizumab induction therapy, was announced in late 2021. The first patient was enrolled in the ongoing Phase 2 portion of the Phase 2/3 study in January 2022, and enrollment in the Phase 2 portion of the study was completed in August 2023. We expect to share preliminary efficacy data from the Phase 2 portion of the Phase 2/3 study in the first quarter of 2024.

SLATE – "Off the shelf" Vaccine Program for Solid Tumors

Our second oncology program, SLATE, consists of "off-the-shelf", TSNA-directed immunotherapy product candidates. SLATE contains a fixed cassette with TSNA that are shared across a subset of cancer patients rather than a cassette unique to an individual patient, which distinguishes it as a potential off-the-shelf alternative candidate to GRANITE. The key differentiator and advantage of SLATE as compared to GRANITE is speed. SLATE vaccines are produced and delivered to clinical sites proactively and can be administered rapidly upon patient selection (achieved by standard commercial screening for driver mutations). We believe vaccines capable of targeting neoantigens from common tumor driver mutations, such as SLATE, have a clear potential clinical utility and commercialization advantages that are complementary to individualized vaccines.

Initial versions of our SLATE vaccine candidates have demonstrated similar results as those seen in GRANITE such as induction of CD8+ T cells, molecular responses among a subset of patients, and an association of these molecular responses with extended overall survival. The strength of the vaccine-elicited immune response was slightly more modest in the SLATE Phase 1/2 results versus those in GRANITE, which is expected given we are delivering one shared TSNA per patient (rather than multiple individualized TSNAs).

Following initial Phase 1 results, we developed a second SLATE candidate that exclusively includes epitopes from mutated KRAS (SLATE-KRAS) and evaluated it under the same protocol. As shared in a presentation at ESMO 2022, results of the SLATE Phase 1/2 study in advanced solid tumors (N = 38) show: consistent induction of CD8+ T cells, a 39% molecular response rate (MRR, molecular response defined as >30% reduction in ctDNA from baseline) in evaluable patients with MSS-CRC and NSCLC and among the 18 patients with NSCLC, a molecular response was correlated with extended mOS (mOS of 9.6 months in molecular responders versus 4.5 months in non-responders).

We believe the results to date demonstrate our ability to both accurately define shared neoantigen targets and engineer the SLATE cassette and vaccine to optimize immune response based on those specific mutations. Having optimized and validated the SLATE cassette, we now believe the SLATE platform is ready for "plug and play" application across solid tumor indications and shared tumor neoantigen classes. In advancing SLATE, we aim to combine the potential benefits of the full spectrum of tumor antigens with the practicality of the "off-the-shelf" approach.

In February 2023, we announced that we entered into a clinical trial agreement with the National Cancer Institute (NCI) to evaluate an autologous T cell therapy expressing a T cell receptor targeting mutated KRAS in combination with our KRAS-directed vaccine candidate, SLATE-KRAS, in a Phase 1 study led by Steven A. Rosenberg, M.D., Ph.D. Under the terms of the agreement, we will provide the SLATE-KRAS vaccine as requested by NCI. An investigational new drug application, or IND, for this study was cleared by the U.S. Food and Drug Administration (FDA) in October 2023. NCI is responsible for conducting the study at the NIH Clinical Center.

Infectious Disease Program Updates

In early 2021, we initiated two programs in infectious diseases: CORAL, a next-generation prophylactic program against COVID-19, and a collaboration with Gilead to develop a therapeutic vaccine against HIV. Our infectious disease programs aim to deliver vaccine candidates that induce both B cell and T cell immunity with the potential to drive potent and durable immune response that can be applied for either protective or therapeutic benefit. This approach has demonstrated the ability to generate robust CD8+ T cells and neutralizing antibodies against SARS-CoV-2 in multiple preclinical and clinical studies and is being evaluated against multiple other pathogens in Gritstone-owned and partnered studies. We believe that initially evaluating our approach against SARS-CoV-2 can provide proof of concept for a number of infectious diseases.

CORAL – Next-Generation COVID-19 Vaccine Program

In October 2023, we announced 12-month follow-up data from two of the Phase 1 trials in our CORAL SARS-CoV-2 vaccine program: CORAL-CEPI and CORAL-BOOST. In our CORAL-CEPI Phase 1 trial, we are evaluating our samRNA-based SARS-CoV-2 vaccine candidates using the Spike proteins from the Beta and Omicron variants with three different antigenic cassettes in unvaccinated populations (Beta vaccine candidates) and unvaccinated and vaccinated populations (Omicron vaccine candidate) in South Africa (n=341). In our CORAL-BOOST Phase 1 dose escalation trial, we are evaluating our samRNA SARS-CoV-2 vaccine candidate as a one or two dose boost regimen in healthy adults who have previously either been vaccinated with the first-generation AstraZeneca SARS-CoV-2 vaccine (n=40) or a mRNA primary series. In the CORAL-BOOST trial, durable nAb titers were increased and maintained through at least six months and broad T cell responses were increased or maintained through six months after adenoviral primary series. In the CORAL-CEPI trial, initial data suggests induction and maintenance of nAb titers through 12 months and an increase and/or maintenance of T cell responses through at least six months (additional nAb and T cell data from the 12-month timepoint are pending).

In October 2023, six-month follow-up data from the CORAL-NIH Phase 1 trial, which is sponsored and executed by the National Institutes of Health (NIH) and National Institute of Allergy and Infectious Diseases (NIAID), were announced. This Phase 1 trial is evaluating our next-generation SARS-CoV-2 vaccine candidate as a boost to first-generation SARS-CoV-2 vaccines. In this trial, at six months, we observed results similar to those in each of our CORAL-CEPI and CORAL-BOOST trials as of six months, including a broad response rate and sustained nAb titer levels.

In all three Phase 1 trials, our next generation SARS-CoV-2 vaccine candidates have been generally well-tolerated, with the majority of adverse events being low grade and transient in nature.

We believe the collective data from these Phase 1 studies demonstrate the potential of our next-generation samRNA vaccines, which contain Spike plus other viral targets, to drive potent and durable clinical protection against COVID-19. We also believe that they demonstrate the potential broad applicability of our novel approach to other infectious disease pathogens.

BARDA Contract

In September 2023, we entered into the BARDA Contract with BARDA. The contract was awarded as part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19.

Under the BARDA contract, which is valued at up to $433.0 million, we are to conduct a 10,000 participant, randomized Phase 2b comparative study to compare the efficacy, safety, and immunogenicity of the Gritstone next-generation COVID-19 vaccine candidate (our samRNA vaccine containing Spike plus other viral targets) with an approved COVID-19 vaccine. The vaccines evaluated in the study are to be tailored to the Omicron XBB.1.5 Spike sequence. Preparations for the study are underway, and we expect to initiate the study in the first quarter of 2024. Gritstone plans to run the study in the United States in collaboration with the COVID-19 Prevention Network (“CoVPN”), a NIAID-supported network of clinical trial sites based at the Fred Hutchinson Cancer Center that has experience conducting large COVID-19 vaccine trials.

The BARDA Contract consists of a base period (ending on or before the first quarter of 2024) and a total contract period-of-performance (base period plus two stages gated at BARDA’s discretion) of up to approximately four years. The base period for the BARDA Contract includes government funding of up to $10.0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new

drug application. Following successful completion of the base period, the BARDA Contract provides for up to approximately $423.0 million of additional BARDA funding for the final two stages gated at BARDA's discretion in support of the clinical trial execution and additional analyses for the clinical trial.

HIV Vaccine Collaboration with Gilead Sciences

In January 2021, we entered into a collaboration, option and license agreement with Gilead to research and develop a vaccine-based immunotherapy for HIV. Together, we plan to develop an HIV-specific therapeutic vaccine using our proprietary prime-boost vaccine platform, comprised of samRNA and adenoviral vectors, with antigens developed by Gilead. The collaboration and the program are progressing, and a Phase I trial is ongoing. If Gilead decides to progress development beyond the Phase 1 study by exercising their exclusive option, the Company will receive a $40.0 million non-refundable option exercise fee.

In February 2023, the first data from a preclinical study conducted in collaboration with Gilead were presented at the Conference on Retroviruses and Opportunistic Infections (CROI) 2023. The results showed that simian immunodeficiency virus (SIV), ChAd and samRNA vaccines induced a strong and broad CD8+ T cell immune response, which was significantly enhanced in combination with immune modulators.

Components of Our Operating Results

Collaboration and License and Grant Revenue

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future. For the three and nine months ended September 30, 2023, we recognized $1.6 million and $6.0 million, respectively, of revenue from the 2seventy Agreement, the Gilead Collaboration Agreement and the grant agreements with CEPI and the Gates Foundation. We recognized $3.0 million and $15.7 million for the three and nine months ended September 30, 2022, respectively, of revenue from the 2seventy Agreement, the Gilead Collaboration Agreement, the CEPI Funding Agreement and the Gates Grant Agreement. See Note 9 to our condensed consolidated financial statements for additional information.

In the future, we expect to continue to recognize revenue from the Gilead Collaboration Agreement, the CEPI Funding Agreement and the Gates Grant Agreement and may generate revenue from product sales or other collaboration agreements, strategic alliances and licensing arrangements. We expect our revenue to fluctuate from quarter-to-quarter and year-to-year as a result of the timing and amount of license fees, milestones, reimbursement of costs incurred and other payments and product sales, to the extent that any are successfully commercialized. If we fail to complete the development of our 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.

Operating Expenses

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies, manufacturing development efforts and related development activities for our product candidates.

Research and development activities account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

- External research and development expenses, including:
  - expenses incurred under arrangements with third parties, including clinical research organizations ("CROs"), preclinical testing organizations, contract manufacturing organizations ("CMOs"), academic and non-profit institutions and consultants;
  - fees related to our license agreements;
- Internal research and development expenses, including (i) headcount-related expenses, such as salaries, payroll taxes, benefits, non-cash stock-based compensation and travel, for employees contributing to

research and (ii) development activities, including the costs associated with the development of our EDGE™ platform; and

- Other expenses, which include direct and allocated expenses for laboratories, facilities and other costs.

Pursuant to our Arbutus License Agreement, Arbutus granted us a worldwide, exclusive license to certain technology of Arbutus, including Arbutus' portfolio of proprietary and clinically validated LNP products and associated intellectual property, as well as technology transfer of Arbutus' manufacturing know-how. During the three and nine months ended September 30, 2023 and 2022, we had no research and development expense under the agreement.

Pursuant to our 2020 Genevant License Agreement, Genevant granted us exclusive license rights under certain intellectual property related to Genevant's LNP technology for a single indication, and we agreed to pay Genevant an initial payment of $2.0 million, and up to an aggregate of $71.0 million in specified development, regulatory, and commercial milestones, and low to mid-single digit royalties on net sales of licensed products. The upfront payment of $2.0 million was included in research and development expense during 2020. In March 2022, a milestone in the amount of $1.0 million was met, which was included in research and development expense for the nine months ended September 30, 2022. No research and development expense was recorded for the three and nine months ended September 30, 2023.

Pursuant to our 2021 Genevant License Agreement, we obtained a nonexclusive license to Genevant's LNP technology to develop and commercialize samRNA vaccines against SARS-CoV-2, the virus that causes COVID-19. Under the 2021 Genevant License Agreement, we made a $1.5 million upfront payment to Genevant, and Genevant is eligible to receive from us up to $191.0 million in contingent milestone payments per product, plus certain royalties on future product sales or licensing (or, in certain scenarios and subject to certain conditions, in lieu of these milestone payments and royalties Genevant would receive a percentage of amounts we receive from sublicenses). In March 2021, a milestone was met following the initial patient treatment in the Phase 1 clinical trial conducted through the NIAID-supported IDCRC. Both the $1.5 million upfront and $1.0 million milestone payments were recorded as research and development expense for the six months ended June 30, 2021. No research and development expense was recorded for the three and nine months ended September 30, 2023 or 2022.

Pursuant to our 2023 Genevant License Agreement, we obtained a multi-year option for a non-exclusive license under Genevant's LNP technology on a pathogen-by-pathogen basis to develop and commercialize samRNA vaccines against infectious disease. Under the 2023 Genevant License Agreement, we made a $2.5 million upfront payment to Genevant, which was included in research and development expense for the three and nine months ended September 30, 2023, and Genevant is eligible to receive from us option maintenance and exercise fees in the single digit millions and up to an aggregate of $136.0 million in contingent milestone payments per product, subject to increase for multi-pathogen products and in other specified circumstances, and royalties ranging from the mid to high single digits on future product sales. If we outlicense an applicable infectious disease program, in lieu of certain of these payments, Genevant may be entitled to a percentage of amounts that we receive from our sublicensee.

We expect our research and development expenses to increase substantially in the future as we continue to advance our product candidates into and through clinical studies and pursue regulatory approval. Conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming, and such clinical studies generally become larger and more costly to conduct as they advance into later stages. The successful development of our product candidates is highly uncertain. The actual probability of success for our product candidates may be affected by a variety of risks and uncertainties associated with drug development, including those set forth in the section entitled "Risk Factors" included in Part II, Section 1A of this Quarterly Report on Form 10-Q and in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and in the section entitled "Risk Factors" included in Part II, Section 1A of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023.

The following table summarizes our research and development expenses by program and category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GRANITE program external expenses	$ 4,599	$ 3,088	$ 15,116	$ 9,232
SLATE program external expenses	201	604	1,544	2,076
CORAL program external expenses	2,322	2,802	5,802	9,002
Other program external research and development expenses	8,590	5,463	20,609	17,702
Personnel-related expenses [(1)]	11,045	10,159	34,057	31,117
Other unallocated research and development expenses	6,006	4,320	17,116	12,854
Total research and development expenses	$ 32,763	$ 26,436	$ 94,244	$ 81,983

(1) Personnel-related expenses include stock-based compensation expense of $1.6 million and $4.8 million, respectively, for the three and nine months ended September 30, 2023, and $1.6 million and $5.1 million, respectively, for the three and nine months ended September 30, 2022.

We do not track internal related expenses on a program-by-program basis, because our research and development employees and infrastructure resources are utilized across our development programs.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, non-cash stock-based compensation and travel. Other general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, and professional service fees for auditing, tax and general legal services. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our current and future product candidates, increase our headcount and support our operations, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with requirements of the Nasdaq Global Select Market and the SEC, directors and officers liability insurance premiums and investor relations activities. Allocated expenses consist of rent expenses related to our office and research and development facilities, depreciation and other allocated costs not otherwise included in research and development expenses.

Interest Income

Interest income consists primarily of interest income and investment income earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists primarily of interest expense related to our debt facility. A portion of the interest expense is non-cash expense relating to the accretion of the final payment fees and amortization of debt discount and debt issuance costs associated with the Loan Agreement.

Results of Operations

Comparison of the three and nine Months Ended September 30, 2023 and 2022

The following table sets forth the significant components of our results of operations (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Revenues:			
Collaboration and license revenues	$ 361	$ 436	$ (75)
Grant revenues	1,204	2,585	(1,381)
Total revenues	1,565	3,021	(1,456)
Operating expenses:			
Research and development	32,763	26,436	6,327
General and administrative	7,406	6,462	944
Total operating expenses	40,169	32,898	7,271
Loss from operations	(38,604)	(29,877)	(8,727)
Interest income	1,167	462	705
Interest expense	(991)	(551)	(440)
Other expense	(6)	—	(6)
Net loss	$ (38,434)	$ (29,966)	$ (8,468)

	Nine Months Ended September 30,		
	2023	2022	Change
Revenue:			
Collaboration and license revenues	$ 1,302	$ 7,942	$ (6,640)
Grant revenues	4,659	7,741	(3,082)
Total revenue	5,961	15,683	(9,722)
Operating expenses:			
Research and development	94,244	81,983	12,261
General and administrative	20,867	22,209	(1,342)
Total operating expenses	115,111	104,192	10,919
Loss from operations	(109,150)	(88,509)	(20,641)
Interest income	4,324	663	3,661
Interest income	(2,818)	(551)	(2,267)
Other expense	(28)	—	(28)
Net loss	$ (107,672)	$ (88,397)	$ (19,275)

Collaboration and License and Grant Revenues

Collaboration and license revenues from our collaboration arrangements and grant revenues were $1.6 million and $6.0 million for the three and nine months ended September 30, 2023, respectively. During the three months ended September 30, 2023, we recorded $0.1 million in collaboration revenue related to the Gilead Collaboration Agreement, $0.3 million in collaboration revenue related to the 2seventy Agreement, $0.8 million in grant revenue from the CEPI Funding Agreement, and $0.4 million in grant revenue pursuant to the Gates Grant Agreement. During the nine months ended September 30, 2023, we recognized $1.0 million in collaboration revenue related to the 2seventy Agreement, $0.3 million in collaboration revenue related to the Gilead Collaboration Agreement, $3.4 million in grant revenue from the CEPI Funding Agreement, and $1.3 million in grant revenue from the Gates Foundation.

Collaboration and license revenues from our collaboration arrangements and grant revenues were $3.0 million and $15.7 million for the three and nine months ended September 30, 2022, respectively. During the three months ended September 30, 2022, we recognized $0.2 million in collaboration revenue related to the 2seventy Agreement, $0.2 million in collaboration revenue related to the Gilead Collaboration Agreement, $2.3 million in grant revenue from the CEPI Funding Agreement, and $0.3 million in grant revenue from the Gates Foundation. During the nine months ended September 30, 2022, we recognized $6.5 million in collaboration revenue related to the 2seventy Agreement, $1.5 million in collaboration revenue related to the Gilead Collaboration Agreement, $6.9 million in grant

revenue from the CEPI Funding Agreement, and $0.8 million in grant revenue from the Gates Foundation. The amount of collaboration revenue recognized related to the 2seventy Agreement during the nine months ended September 30, 2022 included cumulative catch-up adjustments increasing contribution revenue by $5.5 million due to revisions to estimated costs to complete the remaining performance obligation.

See Note 9 to our condensed consolidated financial statements for additional information.

Research and Development Expenses

Research and development expenses were $32.8 million and $94.2 million for the three and nine months ended September 30, 2023, respectively, and $26.4 million and $82.0 million for the three and nine months ended September 30, 2022, respectively.

The increase of $6.3 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was primarily due to increases of $2.5 million in milestone and license payments, $1.0 million in personnel-related expenses, $2.0 million in facilities-related costs, and $0.9 million in outside services, consisting primarily of clinical trial and other chemistry, manufacturing and controls ("CMC") related expenses, offset by decreases of $0.1 million in laboratory supplies.

The increase of $12.3 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to increases of $3.6 million in personnel-related expenses, $1.7 million in laboratory supplies, $5.2 million in facilities related costs, $1.4 million in milestone and license payments, and $0.4 million in outside services, consisting primarily of clinical trial and other CMC related expenses.

General and Administrative Expenses

General and administrative expenses were $7.4 million for the three months ended September 30, 2023 compared to $6.5 million for the three months ended September 30, 2022. The increase of $0.9 million was primarily attributable to increases of $0.5 million in outside services, $0.2 million in personnel-related expenses, and $0.2 million in facilities related costs.

General and administrative expenses were $20.9 million for the nine months ended September 30, 2023 compared to $22.2 million for the nine months ended September 30, 2022. The decrease of $1.3 million was primarily attributable to decreases of $1.8 million in outside services, offset by increase of $0.3 million in facilities related costs, and $0.2 million in personnel-related expenses.

Interest Income

Interest income was $1.2 million and $4.3 million, respectively, for the three and nine months ended September 30, 2023, and $0.5 million and $0.7 million for the three and nine months ended September 30, 2022. The income for both periods represents interest and investment income from cash, cash equivalents and marketable securities. The increase for both periods was primarily due to higher interest rates in 2023 as compared to 2022.

Interest Expense

Interest expense was $1.0 million and $2.8 million for the three and nine months ended September 30, 2023, and $0.6 million for each of the three and nine months ended September 30, 2022. Interest expense is primarily comprised of the contractual coupon interest expense, the amortization of the debt discount and issuance costs and the accretion of the final payment fee associated with the Loan Agreement.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through sales of our convertible preferred stock, sales of our common stock in public offerings and under our "at-the-market" offering programs, private placements of our common stock and pre-funded warrants, and our collaborations, including with the receipt of proceeds under the 2seventy Agreement and the Gilead Collaboration Agreement, and non-dilutive grants from various nonprofit organizations. As of September 30, 2023, we had cash, cash equivalents, and marketable securities of $83.9 million and an accumulated deficit of $628.7 million, compared to cash, cash equivalents, and marketable securities of $175.9

million and an accumulated deficit of $521.1 million as of December 31, 2022. The Company's cash, cash equivalents and marketable securities are not sufficient to fund the Company's planned operations for a period of 12 months from the date the condensed consolidated financial statements included herein are issued. Additionally, we do not expect positive cash flows from operations in the foreseeable future. Historically, we have incurred operating losses as a result of ongoing efforts to develop our vaccine candidates, including conducting ongoing research and development and providing general and administrative support for these operations. We expect to continue to incur net operating losses for at least the next several years as we advance GRANITE, SLATE, and CORAL and any future product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest in our manufacturing facility.

In September 2021, we completed the Second PIPE Financing, pursuant to which we sold an aggregate of 5,000,000 shares of common stock at a per share purchase price of $11.00. In connection with the Second PIPE Financing, we received $55.0 million in aggregate gross cash proceeds and incurred related costs of $2.3 million.

In February 2021, we received a non-refundable upfront payment of $30.0 million under the Gilead Collaboration Agreement and $30.0 million under the Gilead Stock Purchase Agreement.

In September 2021, we received an upfront payment of $11.3 million under the CEPI Funding Agreement.

In March 2022, we filed the 2022 Shelf Registration Statement, covering the offering of up to $250.0 million of various equity and debt securities, including the sale and issuance of up to $100.0 million worth of shares of our common stock under the 2022 ATM Offering Program. Through September 30, 2023, we have received aggregate proceeds from our 2022 ATM Offering Program of $22.1 million, net of commissions and offering costs, pursuant to the issuance of 7,889,000 shares. As of September 30, 2023, we have $77.2 million available under the 2022 ATM Offering Program.

In April 2022, we received the second tranche payment of $2.7 million under the CEPI Funding Agreement.

In July 2022, we entered into the Loan Agreement with Hercules and SVB, which provides us with a 60-month term loan facility for the Company up to $80.0 million in borrowing capacity across five potential tranches. At the closing of the Loan Agreement, we drew $20.0 million from the first tranche, and we drew an additional $10.0 million in March 2023. The remaining tranches provide up to $50.0 million borrowing capacity and become available if and when we meet certain milestones set forth in the Loan Agreement. In the fourth quarter of 2022, one milestone had been achieved, which provides the Company the ability to draw up to $10.0 million through December 15, 2023. As of September 30, 2023, the Company has not drawn the additional $10.0 million. The term loan is secured by substantially all of our assets, other than intellectual property. There are no warrants associated with the Loan Agreement. See Note 8 to our condensed consolidated financial statements for additional information.

In March 2023, Gritstone, Hercules and SVB entered into the First Amendment to amend the minimum liquidity requirements under the Loan Agreement. Under the Amended Loan Agreement, beginning on the earliest occurrence of certain milestones or April 1, 2024, and at all times thereafter, so long as our market capitalization is no greater than $400.0 million, we are subject to a minimum liquidity requirement equal to the then outstanding balance under the Loan Agreement multiplied by 0.55 or 0.45, which multiplier depends on whether we achieve certain performance milestones.

In October 2022, we completed the Third PIPE Financing, pursuant to which we sold an aggregate of 6,637,165 shares of common stock at a per share purchase price of $2.26 and pre-funded warrants to purchase 13,274,923 shares of common stock at a price of $2.26 per share (of which $2.2599 per share was prepaid by each purchaser). The aggregate gross cash proceeds to us for the securities sold in the Third PIPE Financing was $45.0 million, and related costs were $2.6 million.

In April 2023, we received $0.7 million under the Gates Grant Agreement.

In June 2023, we received the third tranche payment of $1.2 million under the CEPI Funding Agreement.

Future Funding Requirements

We do not expect positive cash flows from operations in the foreseeable future. Historically, we have incurred operating losses as a result of ongoing efforts to develop our cancer and infectious disease immunotherapy candidates, including conducting ongoing research and development, clinical and preclinical studies and providing general and administrative support for these operations. We do not have any products approved for sale, and we do not expect to

generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our current and future product candidates and/or enter into additional significant collaboration or grant agreements with third parties. We do not know when, or if, either will occur. We expect to continue to incur net operating losses for at least the next several years and we expect the losses to increase as we advance our GRANITE, SLATE, and CORAL programs, as well as any future product candidates, through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest in our manufacturing facility. We are subject to all the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we incur substantial costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of immunotherapy product candidates or from additional significant collaboration or license agreements with third parties, if ever, we expect to finance our future cash needs through private and public equity offerings, including our "at-the-market" offering programs, debt financings, and potential future collaboration, license and development agreements. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our current or future product candidates. If we raise additional funds by issuing equity or convertible debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Any of the foregoing could significantly harm our business, financial condition and prospects.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $628.7 million as of September 30, 2023. We expect to incur substantial additional losses in the future as we conduct and expand our research and development activities. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of the issuance of our unaudited interim condensed consolidated financial statements. The accompanying unaudited interim condensed consolidated financial statements and related notes have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The unaudited interim condensed consolidated financial statements and related notes do not reflect any adjustments relating to the recoverability and classification of assets or amounts and classification of liabilities that might be necessary if we are unable to continue as a going concern.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of developing our product candidates, and of conducting preclinical studies and clinical trials, including our clinical trials for GRANITE, SLATE and CORAL;
- the timing of, and the costs involved in, obtaining regulatory approvals for our oncology and infectious disease immunotherapy product candidates; in particular, any costs incurred in connection with any future regulatory requirements that may be imposed by the FDA or foreign regulatory bodies;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements;
- the cost of manufacturing our product candidates we successfully commercialize, including the cost of scaling up our internal manufacturing operations;

- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities, including building a commercial infrastructure, marketing, sales and distribution costs;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the costs to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of future approved products, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will need additional funds to meet operational needs and capital requirements associated with such operating plans.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Cash used in operating activities	$ (102,140)	$ (85,572)
Cash provided by investing activities	64,046	33,188
Cash provided by financing activities	9,400	18,733
Net decrease in cash and cash equivalents	$ (28,694)	$ (33,651)

Cash Used in Operating Activities

During the nine months ended September 30, 2023, cash used in operating activities was $102.1 million, which consisted of net loss of $107.7 million, adjusted by non-cash charges of $23.3 million and net changes in our operating assets and liabilities of $17.7 million. The non-cash charges consisted primarily of depreciation and amortization expense of $5.7 million, amortization of debt discount and issuance costs of $0.9 million, stock-based compensation of $8.8 million and non-cash operating lease expense of $10.3 million, partially offset by net amortization of premiums and discounts on marketable securities of $2.4 million. The change in our operating assets and liabilities was primarily due to decreases of $0.4 million in accrued compensation, $3.3 million in accrued and other non-current liabilities, $14.9 million in lease liability, $3.8 million in deferred revenue, $1.4 million in accounts payable, offset by increases of $0.4 million in accrued research and development expense, $4.3 million in deposits and other long-term assets and $1.4 million in prepaid expenses and other current assets.

During the nine months ended September 30, 2022, cash used in operating activities was $85.6 million, which consisted of net loss of $88.4 million, adjusted by non-cash charges of $21.6 million and net changes in our operating assets and liabilities of $18.8 million. The non-cash charges consisted primarily of depreciation and amortization expense of $4.8 million, stock-based compensation of $9.5 million, non-cash operating lease expense of $6.9 million and net amortization of premiums, discounts on marketable securities of $0.3 million, and amortization of debt discount and issuance costs of $0.1 million. The change in our operating assets and liabilities was primarily due to decreases of $11.6 million in deferred revenue, $0.2 million in accrued compensation, $6.5 million in lease liability, $0.9 million in accounts payable, and $3.2 million in deposits and other long term assets, offset by increases of $1.5 million in accrued and other non-current liabilities, $1.3 million in accrued research and development expenses, and $0.8 million in prepaid expenses and other current assets.

Cash Provided by Investing Activities

During the nine months ended September 30, 2023, cash provided by investing activities was $64.0 million, which consisted of $91.1 million in proceeds from the maturity of marketable securities, offset by $22.7 million in purchases of marketable securities and $4.4 million of capital expenditures to purchase property and equipment.

During the nine months ended September 30, 2022, cash provided by investing activities was $33.2 million which consisted of $102.2 million in proceeds from the maturity of marketable securities, offset by $64.6 million in purchases of marketable securities and $4.4 million of capital expenditures to purchase property and equipment.

Cash Provided by Financing Activities

During the nine months ended September 30, 2023, cash provided by financing activities was $9.4 million, which primarily consisted of $9.9 million in proceeds from long-term debt, net of debt discount and issuance costs, $2.6 million in proceeds from the issuance of common stock under the 2022 ATM Offering program, and $0.5 million in proceeds from the issuance of common stock under the employee stock purchase plan, offset by $2.5 million in financing and offering costs, $0.9 million in taxes paid related to net share settlement of restricted stock units and $0.2 million in payment of financing lease.

During the nine months ended September 30, 2022, cash provided by financing activities was $18.7 million, which primarily consisted of $19.2 million in proceeds from long-term debt, $0.2 million in proceeds from the 2022 ATM Offering Program, $0.2 million in proceeds from the issuance of common stock from option and warrant exercises and $0.3 million in proceeds from issuance of common stock under the employee stock purchase plan, offset by $0.9 million in tax withholding on vesting of restricted stock units, $0.1 million in payment of financing costs, and $0.2 million in payment of financing lease.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined under SEC rules.

Contractual Obligations and Commitments

We lease office, laboratory and storage space in facilities at several locations in California and Massachusetts. The terms of our lease agreements have expiration dates between 2023 to 2033. The total future minimum lease payments under the agreements are $99.1 million, of which $2.4 million of the payments are due in 2023. See Note 6 to our condensed consolidated financial statements.

We are party to license agreements pursuant to which we have in-licensed various intellectual property rights. The license agreements obligate us to make certain milestone payments related to achievement of specified events, as well as royalties in the low-single digits based on sales of licensed products. During the three and nine months ended September 30, 2023 and 2022, no royalties were due from the sales of licensed products. The table above does not include any milestone or royalty payments to the counterparties to these agreements as the amounts, timing and likelihood of such payments are not known. See Note 9 to our condensed consolidated financial statements for additional information.

From time to time, in the normal course of business, we enter into contracts with CROs for clinical trials, CMOs for clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice. Therefore, all such contracts are cancelable contracts and not included in the table above.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of financial condition and results of operation is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to preclinical study trial

accruals, fair value of assets and liabilities, and the fair value of common stock and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

There have been no changes to our critical accounting policies since we filed our Annual Report on Form 10-K for the year ended December 31, 2022 with the SEC on March 9, 2023. For a description of our critical accounting policies, please refer to that Annual Report on Form 10-K.

Recent Accounting Pronouncements

Refer to Note 2. Summary of Significant Accounting Policies in the notes to our unaudited interim condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report, for a discussion of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

There have been no material changes in market risk from the information provided in "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2022.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of September 30, 2023, our management, with the participation of our principal executive, financial and accounting officers, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the principal executive, financial and accounting officers, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2023, the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(e) and 15d-15(e) of the Exchange Act that occurred during the three months ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and time and other factors.

ITEM 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below, or in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC on March 9, 2023 and any subsequent quarterly filings could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic, inflation, the high interest rate environment, and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

There have been no material changes to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023, Part II, Item 1A of our Quarterly Report on Form 10-Q for the months ended March 31, 2023 filed with the SEC on May 11, 2023, and Part II, Item 1A of our Quarterly Report on Form 10-Q for the months ended June 30, 2023 filed with the SEC on August 9, 2023, except as set forth below.

A significant portion of the funding for the continued development of our next-generation samRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19 is currently expected to come from the BARDA Contract, and if BARDA were to decline to pursue any of the gated stages, eliminate, reduce, delay, or object to extensions for funding available to us under the BARDA Contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding.

We anticipate that a significant portion of the funding for the continued development of our next generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19 will come from the BARDA Contract. The BARDA Contract provides for funding of up to an estimated $433.0 million to conduct a 10,000 participant randomized Phase 2b comparative study evaluating our self-amplifying RNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The base period under the BARDA Contract includes government funding of only up to approximately $10.0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. Our ability to receive any of the remaining $423.0 million in additional funding provided for under the BARDA Contract is dependent on BARDA electing to continue to fund additional two gated stages, which it may do or not do at its sole discretion. The base period for performance under the BARDA Contract runs from September 2023 to March 2024. The option periods for the two additional gated stages run from January 2024 to March 2026 and from July 2024 to July 2026. In addition, BARDA is entitled to terminate the BARDA Contract for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. In addition, activities covered under the base period may ultimately cost more than is covered by the BARDA Contract and may require a longer performance period to complete than is remaining under the terms of the BARDA Contract. BARDA is not required to provide funding above the approximately $10.0 million currently obligated for the base period of the BARDA Contract, nor is BARDA required to extend the base period of performance or elect to pursue any of the gated stages. If activities covered under the base period cost us more than the approximately $10.0 million currently obligated for the base period under the BARDA Contract, and we are unable to secure additional funding from BARDA to complete performance of the base period activities, we would have to bear the cost to complete the activities. Further, if we are unable to complete the base period activities during the base period due to circumstances that may be either within or outside of our control,

including, among others, any potential delays in sourcing an approved comparator vaccine, and BARDA is unwilling to allow for additional time, then BARDA may decide to terminate the BARDA Contract.

Moreover, the continuation of the BARDA Contract primarily depends on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. Further, as an organization, we are relatively new to government contracting and the related regulatory compliance obligations, and are continuing to develop and implement our internal compliance processes. BARDA may suspend or terminate the BARDA Contract should we fail to achieve key milestones or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols, and there can also be no assurance that the BARDA Contract will not be terminated, that the BARDA Contract will be extended through the exercise of the gating periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under the BARDA Contract. The availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If the BARDA Contract is terminated or suspended, if there is any reduction or delay in funding under the BARDA Contract, or if BARDA determines not to elect to pursue any of the gated stages under the BARDA Contract, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities for our next-generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19, which could materially harm our business.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1(a)	Amended and Restated Certificate of Incorporation.	8-K	10/02/2018	3.1	
3.1(b)	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	05/06/2021	3.1	
3.2	Amended and Restated Bylaws.	8-K	05/06/2021	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	09/17/2018	4.2	
4.3	Description of Common Stock.	10-K	03/10/2022	4.3	
10.1#	Contract between the Company and the Biomedical Advanced Research and Development Authority, dated September 27, 2023.				X
10.2#	Nonexclusive License and Development Agreement between the Company and Genevant Sciences GmbH, dated as of January 15, 2021.				X
10.3#	Amendment No.1 to Nonexclusive License and Development Agreement between the Company and Genevant Sciences GmbH, dated as of January 29, 2021.				X
31.1	Certification of Chief Executive Officer of Gritstone bio, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Chief Financial Officer of Gritstone bio, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification by the Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).				X

101.INS	Inline XBRL Instance Document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 has been formatted in Inline XBRL.	X

* The certification attached as Exhibit 32.1 that accompanies this report is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Gritstone bio, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

Portions of the exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of any omitted portions will be furnished to the SEC upon request.

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.

Gritstone bio, Inc.

Date: November 8, 2023

By: /s/ Andrew Allen
Andrew Allen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Vassiliki Economides
Vassiliki Economides
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) ☑	RATING	PAGE OF PAGES 1 2
2. CONTRACT *(Proc. Inst. Ident.)* NO. 75A50123C00062	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS320156	
5. ISSUED BY CODE	ASPR-BARDA	6. ADMINISTERED BY *(if other than Item 5)* CODE	ASPR-BARDA
ASPR-BARDA 200 Independent Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUT 200 INDEPENDENT AVE, S.W. Washington DC 20201 SCD-C		
7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* GRITSTONE BIO INC [***] MATTHEW HAWRYLUK ; 5959 HORTON STREET 5959 HORTON STREET SUITE 300 EMERYVILLE CA 94608 CODE [***]	8. DELIVERY FORMCHECKBOX FOB ORIGIN FORMCHECKBOX OTHER *(See below)* 9. DISCOUNT FOR PROMPT PAYMENT 10. SUBMITTED INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ☑ FACILITY CODE	ITEM	
11. SHIP TO/MARK FOR CODE	08	12. PAYMENT WILL BE MADE BY CODE	PSC
Office of the Secretary Office of the Secretary 200 Independent Ave. S.W. Washington DC 20201	PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814		
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPEITION. FORMCHECKBOX 10 U.S.C. 2304(c) ( ) FORMCHECKBOX 41 U.S.C. 3304 (a) ( )	14. ACCOUNTING AND APPROPRIATION DATA 2023.199n003.25106		

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
				15G. TOTAL MOUNT OF CONTRACT ☑	$9,856,008.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I – THE SCHEDULE				PART II – CONRACT CLAUSES			
	A.	SOLICITATION/CONTRACT FORM		X	I	CONTRACT CLAUSES	55
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4	PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	11	X	J	LIST OF ATTACHMENTS	63
X	D	PACKAGING AND MARKING	13	PART IV – REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTNACE	14		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	15				
X	G	CONTRACT ADMINISTRATION DATA	30		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	37		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. FORMCHECKBOX CONTRACTOR'S NEGOTIATED AGREEMENTS *(Contractor is required to sign this document and return _____ 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. FORMCHECKBOX SEALED-BID AWARD *(Contractor is not required to sign this document.)* Your bid on Solicitation Number _____ includes 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)* Andrew Allen, CEO	20A. NAME OF CONTRACTING OFFICER Erin W. Greninger
19B. NAME OF CONTRACTOR BY /s/ Andrew Allen, CEO *(Signature of person authorized to sign)* 19C. DATE SIGNED 26 Sep 2023	20B. UNITED STATES OF AMERICA BY /s/ Erin W. Greninger-S *(Signature of the Contracting Officer)* 20C. DATE SIGNED 2023.09.27

AUTHORIZED FOR LOCAL REPRODUCTION STANDARD FORM 26 (Rev. 3/2013)
Previous edition is NOT usable Prescribed by GSA – FAR (48 CFR) 53.214(a)

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 47-4859534 UEI: [***] OTA: N Delivery: 09/28/2023 Appr. Yr.: 2023 CAN: 199N003 Object Class: 25106 Period of Performance: 09/30/2023 to 03/31/2024				
1	ASPR-23-02513 The Base period award is to conduct and complete all planning and preparation efforts needed to execute a Phase 2b clinical trial Obligated Amount: $9,856,008.00				9,856,008.00
2	Option 1 Amount: $[***] (Option Line Item)				0.00
3	Option 2 Amount: $[***] (Option Line Item)				0.00

CONTENTS

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

.1. BRIEF DESCRIPTION OF SERVICES

Current vaccines against COVID-19 lose protective immunity over time, reducing their benefit to individuals and our health systems. Developing a next-generation vaccine that drives (a) more durable and broad anti-Spike neutralizing antibodies (nAbs) against variants of concern (VOCs), including those not included in the vaccine, and (b) T cells reactive against conserved targets in the SARS-CoV-2 genome could serve as a key factor in delivering long-term, variant-proof clinical protection. Gritstone has developed an optimized and clinically validated self-amplifying mRNA (samRNA) vaccine that embodies these requirements and is differentiated from first-generation mRNA vaccines in several key dimensions, including (1) high and prolonged antigen expression relative to non-replicating mRNA, which enables lower dose administration; (2) inclusion of multiple pathogens/antigenic determinants into single products; and (3) a durable nAb response for at least 6 months after vaccination. Broad T cell responses against Spike and other conserved viral epitopes, provide a second pillar of immune protection and are an important component of lasting immunity against COVID-19, especially against newly arising VOCs and severe disease. Gritstone's samRNA COVID-19 vaccine delivers [***]. Gritstone's samRNA is a potent next-generation vaccine that may extend protection against SARS-CoV-2 by eliciting prolonged and broad humoral and cellular immune responses.

The Government has determined a Bona Fide Need for each non-severable discrete work segment which will conclude upon the completion of a defined task or defined tasks that provide(s) independent merit and value to the Government. The Contractor's success in completing the required tasks under the work segments must be demonstrated through the Deliverables and Milestones specified under Article F of this contract. As set forth in the Contract WBS Milestones/Deliverables and Technical Deliverables chart under Article F of this contract, the GO/NO GO Contract Milestones and Decision Gates will constitute the basis for the decision to exercise any follow-on option period(s).

The base period (Contract Line Item (CLIN) 001) and option periods (CLINs 002 and 003) will follow the periods of performance as detailed in B.2 and B.3, and option periods may run concurrently. The base period will operate on a firm-fixed-price basis with fixed payments per deliverable, and the option periods will operate on a cost-plus-fixed-fee basis for the costs incurred.

.2. FIRM-FIXED PRICE BASE PERIOD

The estimated costs and periods of performance associated with this Firm-Fixed-Price base period contract with Gritstone are reflected below.

1. **The Government's total cost for the base period contract is $9,856,008.00.**
2. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 (Oct 2010), Audit and Records-Negotiation. incorporated by reference into this contract in SECTION I.

   Pursuant to FAR 52.232-2, BARDA will make partial payments upon receipt and acceptance of a deliverable and acceptable invoice for partial delivery of work, as outlined in Table 2.
3. The amount currently obligated will cover the Base Period (CLIN 0001) of the contract from 9/30/2023 – 03/31/2024 (see table below) unless FAR Clause 52.217-8 is exercised. The period of performance and deliverables may be adjusted by mutual agreement in a bilateral modification between the Contractor and the Government.

Table 1. BASE PERIOD

CLIN	Base Period of Performance	Deliverable	Base Period Total Cost
0001	09/30/2023– 3/31/2024	See Table 2	$9,856,008.00

Table 2. BASE PERIOD DELIVERABLES AND ASSOCIATED MILESTONE PAYMENTS

Partial Pymt.	SOW Para.	Deliverable Title	Brief Description of Deliverable	Partial Payment Amount	Time After Contract Award
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

.3. COST REIMBURSABLE OPTION PERIODS

1. Pursuant to FAR 52.217-9, Option to Extend the Term of the Contract (Mar 2000), set forth in full in ARTICLE I.2 of this Contract, the Government may unilaterally agree that the Contractor will perform discrete portions of additional work as specified in the Statement of Work.

2. Unless the Government exercises the contract options pursuant to the option clauses contained in ARTICLE I.2, the contract consists only of the base period deliverables, CLIN 0001, specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in ARTICLE B.2 of the contract.

3. The Government may exercise options and may require the Contractor to provide services for Option Periods listed below, in accordance with FAR 52.217-9 or FAR 52.217-8.

4. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary notice of its intent as referenced in the FAR clause. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION I of this contract. The estimated cost of the contract will be increased as set forth below:

5. If FAR Clause 52.217-8 Option to Extend Services, is exercised, the current costs (direct, indirect, fringe, material, subcontracting and etc.) shall remain unchanged.

6. The Governments total cost for the option periods of the contract is **$423,334,524.00**.

OPTION PERIODS

CLIN	Option Period of Performance	Deliverables	Cost	Fixed Fee	Option Periods Total Costs
0002	**Option Period 1 01/01/2024 – 03/01/2026**	Attachment 1 – Statement of Work Part II	[***]	[***]	[***]
0003	**Option Period 2 07/01/2024 – 07/02/2026**	Attachment 1 – Statement of Work Part III	[***]	[***]	[***]
Option Period Total Cost			[***]	[***]	**$423,334,524.00**

B.5. LIMITATIONS APPLICABLE TO DIRECT COSTS

1. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses and unless authorized in writing by the Contracting Officer or set forth in the Statement of Work, the cost of the following items or activities shall be unallowable as direct costs:

a. Acquisition, by purchase or lease, of any interest in real property;

b. Special rearrangement or alteration of facilities;

c. Accountable Government Property (see the HHS Contracting Guide for Control for Government Property incorporated by Section G.10. of this contract);

Note: this includes the lease or purchase of any item of general-purpose office furniture or office equipment regardless of dollar value.

d. Purchase or lease of scientific instruments or equipment over $10,000 except for instruments and equipment specifically included in the Statement of Work;

e. Travel to attend general scientific meetings/conferences;

f. Printing Costs (as defined in the Government Printing and Binding Regulations);

g. Overtime (premium) compensation;

h. Entering into certain types of subcontracting arrangements (See Section B.5(6) for specific obligations). Note that most consulting agreements require CO's written consent;

i. Foreign Travel (see Section B.5.2 Travel Costs);

j. Patient care costs (see Section J-List of Attachments);

k. Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least [***] in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications."

The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

2. Travel Costs

Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract during the base period and option periods shall not exceed the amounts shown in the table below without the prior written approval of the CO. The Contractor shall notify the CO in writing when travel expenditures have exceeded [***] of the base period and option periods' travel expenses.

CLIN	Period	Amount
0001	Base	[***]
0002	Option Period 1	[***]
0003	Option Period 2	[***]

Subject to the dollar limitation specified above, the Contactor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulation (FAR) 31.2 – Contracts with Commercial Organizations, Subsection 31.205- 46, Travel Costs and GSA Per Diem Rates.

If foreign travel is necessary, a Contracting Officer Authorization (COA) will be required. Expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed the amount specified in each approved COA, without the prior written approval of the Contracting Officer.

Requests for foreign travel must be submitted at least four (4) weeks in advance and shall contain the following:

(a) meeting(s) and place(s) to be visited, with costs and dates; name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;

(b) contract purposes to be served by the travel;

(c) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of ASPR contract funds;

(d) how such advantages justify the costs for travel and absence from the project of more than one (1) person if such are suggested; and

(e) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

B.6. ADVANCE UNDERSTANDINGS

1. This contract is for the preparation, completion, and analysis of a Phase 2b clinical trial. **[***].**

2. Certain sections of this contract refer to requirements that are applicable to activities outside the Statement of Work as of the effective date of the contract. Such sections include, but are not limited to: Sections B.6.6, B.6.15, B.6.16, C.6, H.1.1, H.35, H.36. For clarity, the Contractor will comply with the requirements set forth in these or any other sections only if applicable to the activities in the Statement of Work as of the effective date of the contract or resulting modification.

3. The type of contract is a hybrid contract with a Firm-Fixed-Price Base Period and two Cost Plus Fixed Fee Option Periods.

4. The Option Periods contained in Article I.2 will be exercised by a unilateral modification and notification by the Government to the Contractor. BARDA may effect certain administrative changes unilaterally. The study results and learnings from the base period Statement of Work will inform or form the basis for the decision to exercise the FAR options, pivot or stop the program.

5. Gritstone's approved and not to exceed ceiling rates for the option periods of the contract are shown in the table below:

Category	Approved Rate	Not to Exceed Rate	Description
Fringe Benefits	[***]	[***]	Total salaries and wages
Labor Overhead	[***]	[***]	Total direct labor plus allocated fringe costs
G&A	[***]	[***]	Total direct costs excluding total subcontract costs

Any change to these rates must be supported by an approved audit from an acceptable Government agency and incorporated into the contract by bilateral modification.

6. Person-in-Plant

With [***] advance notice to the Contractor in writing from the Contracting Officer, the Government may place a person-in-plant in the Contractor's or Subcontractor's facility, who shall be subject to the Contractor's or

Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility. The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. 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 or subcontractor plant.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

7. Confidential Treatment of Sensitive Information

As a supplement to Section H.19 of the contract, the Contractor shall guarantee strict confidentiality of any information/data of a sensitive nature that is provided to the Contractor by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature and will be marked as so. Disclosure of information/data that is sensitive in nature, 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/data under the contract, the Contractor shall obtain a written determination from the CO (see also HHSAR clause 352.224- 71). Notwithstanding the foregoing, such information/data shall not be

deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor at or prior to the time of its disclosure to the Contractor; (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/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or nonuse, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

The Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given notice to the Government and give the Government a reasonable opportunity to quash such order and to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) otherwise required by law, in the opinion of legal counsel to the Contractor as expressed in an opinion letter in form and substance reasonably satisfactory to the Government, which shall be provided to the Government at least [***] prior to the Contractor's disclosure of the information/data; 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/data.

8. Invoice Submission during end of Fiscal Year

The government will not accept invoices for processing from Sep 6th through Oct 5th because of end of year fiscal requirements. Any invoices received from September 6th through October 5th will be canceled and returned to the Contractor for resubmission beginning on October 6th.

9. 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: 75A50123C00062

10. Subcontracts

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

Is of the cost-reimbursement, time-and-materials or labor-hour type or
Is of the fixed price type and exceeds [***] or [***] of the contract, whichever is less

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer within [***].

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Section.

11. Overtime Compensation

[***]

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

Subject to the data rights provisions of FAR 52.227-14 and 52.227-14 Alt. II, in an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the

Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with the United States Government and entities within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial or technical information, technical deliverables, or any other data outside of the United States Government. 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.

13. Approval of Human and Animal Protocols

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval prior to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government shall perform review within [***]. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

14. Rights in Data

The Contract will incorporate the FAR Clause 52.227-14, Rights in Data—General and 52.227-14 Alt II. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables. Notwithstanding the incorporation of the above-stated FAR clauses into this Contract or any other provision herein, however, Contractor shall not be required to disclose or provide access to any source code for computer software (including design details, algorithms, processes, flow charts, formulas and related material from which such source code can be readily developed) or trained AI models unless Contractor agrees otherwise in a deliverable that expressly requires such disclosure.

BARDA agrees that all data furnished under the Contract marked with the "limited rights" legend contained in FAR

52.227-14 Alternate II shall be treated in accordance with all "limited rights" restrictions and protections described in FAR 52.227-14 Alternate II. BARDA shall not disclose or use any data marked with the "limited rights" legend for any purpose except as specifically authorized by the "limited rights" provision in FAR 52.227-14 Alternate II, or by any express license agreement between the Government, Gritstone, and if necessary, a third party. BARDA further agrees to take all reasonable steps necessary to ensure that no other party obtains access to Gritstone's intellectual property that is marked with the "limited rights" legend.

Limited Rights Data is defined as data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

Where delivery of Limited Rights Data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (Dec 2007)

These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

(i) Use (except for manufacture) by support service contractors.
(ii) Evaluation by nongovernment evaluators.
(iii) Use (except for manufacture) by other contractors participating in the Government's program of which the specific contract is a part

This notice shall be marked on any reproduction of these data, in whole or in part.

15. Emergency Use Authorization (EUA)

It is anticipated that the product 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). 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.

For information concerning EUA, please consult http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127 and http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm

16. Security Plan

If applicable, the Contractor shall submit a security plan for review and approval within [***] of contract award.

17. [***]

[***]

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. 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 attached to this contract as Attachment 1 (Section J-List of Attachments).

C.2. REPORTING REQUIREMENTS

Refer to Section F.2 for specific instructions regarding Reporting Requirements.

C.3. PROJECT MEETING CONFERENCE CALLS

A conference call between the Contracting Officer, the Contracting Officer's Representative (COR) and designees and the Contractor's Project Leader/delegate and designees shall occur [***] or as otherwise mutually agreed upon by the Government and the Contractor or determined by the Contracting Officer. Teleconferences may be more or less frequent at the request of the CO 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 Contracting Officer's Representative. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded into a new "Collaborator Portal" by the Contractor within [***] after the conference call is held. The new "Collaborator Portal" is not (at the time of contract award) 100% online for use. The COR shall provide details and setup instructions for the portal once it is authorized for use.

C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the COR. These meetings may include virtual and/or face-to-face meetings with BARDA at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and Government personnel as required by the COR in order to facilitate review of contract activities.

1. Kickoff Meeting

The Contractor and Government shall conduct a kickoff meeting within [***] after contract award to review HHS procedures, processes and expectations. Contractor shall provide an itinerary/agenda no later than [***] before meeting. Minutes from the kickoff meeting must be provided within [***] of the event.

2. Quarterly and Ad-Hoc Meetings

At the discretion of the CO or COR, the Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the COR. These meetings may be conducted via virtual or face-to-face meetings in Washington, D.C. or at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor's confidential or proprietary data) and Government personnel as required by the Contracting Officer's Representative, giving reasonable prior notice of such requirement to Contractor, in order to facilitate review of contract activities.

Contractor shall provide itinerary/agenda at least [***] in advance of meetings.

Contractor shall provide a meeting summary to the BARDA COR no later than [***] after the meeting.

3. Project Review Meetings

The Contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a virtual or face-to-face meeting in Washington, DC., or, alternatively upon agreement of the parties a virtual or

remote meeting. The Contractor will be responsible for updating the BARDA program on technical progress under the Statement of Work. Presentation must be delivered [***] prior to the scheduled meeting.

C.5. REGULATORY ACTIVITIES

The Contractor shall provide access to all Contractor Standard Operating Procedures (SOPs) upon request from Contracting Officer's Representative/Contracting Officer. SOPs are used for audit purposes and validation of the programs progress. Authorized reviewers of the SOPs shall provide non-disclosure agreements, if required.

C.6. QUALITY

The Contractor shall establish and maintain a Quality Management System with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor shall establish routine internal reviews, documentation, and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor shall contract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government. Such audits are conducted by individuals who do not have direct responsibility for the matters being audited. The Contractor shall provide a summary of the Quality Audit Findings and resolutions from its last audit to the Government.

SECTION D - PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be provided in accordance with Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E - INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following 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. Also, the full text of a clause may be accessed electronically at: https://www.acquisition.gov/FAR/ HHSAR

Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

FAR Clause Title and Date

FAR 52.246-3, Inspection of Supplies – Cost-Reimbursement (May 2001)
FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)
FAR 52.246-8, Inspection of Research and Development – Cost Reimbursement (May 2001)
FAR 52.246-16, Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

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 or authorize any changes in the Statement of Work or modify or extend the period of performance or authorize reimbursement of any costs incurred during performance.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the services and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection, and acceptance will take place at a location designated by the Contracting Officer or the Contracting Officer Representative.

1. Site Visits and Inspections

At the discretion of the Government and independent of activities conducted by the Contractor, with [***] notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the [***] notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

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:

a. If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within [***] detailing the finding and corrective action(s) of the audit.

b. COR and CO will review the report and provide a response to the Contractor within [***].

c. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F - DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2. If the Government exercises the Options Period(s) pursuant to the Option Clause in Article I.2 of the contract, the period of performance shall be increased as shown in the tables in Section B.3.

F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 “Summary of Contract Deliverables” in accordance with the stated delivery schedule.

The items specified below under heading 1 “Summary of Contract Deliverables” and as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. Summary of Contract Deliverables

Unless otherwise stated, each deliverable in the table below shall be provided as one electronic copy to the Contracting Officer's Representative, Contract Specialist, and Contracting Officer as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	**Meetings**		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
02	**Technical Reporting**		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
03	**Audits**		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
04	**Regulatory Documents**		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
05	**Press Release**		
[***]	[***]	[***]	[***]

2. Detailed Description of Select Contract Deliverables

A. Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Article F of this contract, and in the Statement of Work, attached to this contract as Attachment 1 (SECTION J-List of Attachments).

i. 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 according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this article. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

The format should include:

- A cover page that includes 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;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
    - SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
    - SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - 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).
    - SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost 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. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report 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; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Updated Gantt chart should be included in report, including description of any changes made since the prior month.
    - SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
    - SECTION III: Actual Expenses. This section of the report shall contain actual expenses and should be broken down to the appropriate WBS level.

Report should include a tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps.

A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

Each Annual Progress Report shall include:

A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;

- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
  - SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
  - SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (*e.g.* regulatory compliance audits and key personnel changes).
  - SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
  - SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.
  - SECTION III: Actual Expenses. This section of the report shall contain actual expenses and should be broken down to the appropriate WBS level, to the extent applicable.

    Contractor also should include the following in the Annual Progress Report:

  Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

  A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps.

iii. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

2. 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.

3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2. of this contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

iv. Draft and Final Reports for Clinical Studies

- The clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 “Guideline for Industry on Structure and Content of Clinical Study Reports”
- Draft Final Report for Clinical Studies funded by this contract will be submitted to the Contracting Officer’s Representative and Contracting Officer (CO) for review and comment within the time frames set forth in the table (“Summary of Contract Deliverables”) under ARTICLE F.2.
- Subcontractor prepared reports received by the Contractor shall be submitted to the Contracting Officer’s Representative and Contracting Officer (CO) for review and comment as set forth by the table in this Article. Contractor shall consider revising reports to address BARDA’s recommendations prior to FDA submission.
- The Government shall provide written comments to the Draft Final Report for Clinical Studies in accordance with the dates set forth by the table in this Article.
- The comprehensive Final Report for Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer’s Representative set forth by the table in this Article.

v. Supplemental Technical Documents

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating

Procedures (SOP’s), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the USG. Contractor shall provide technical document within [***] of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to two subject matter experts).

Contractor shall notify BARDA of upcoming FDA meeting within [***] of scheduling Type A, B or C meetings OR within [***]of meeting occurrence for ad hoc meetings.

The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within [***] of receipt. All documents shall be duly marked as either “Draft” or “Final.”

ii. FDA Submissions

The Contractor shall provide BARDA all documents submitted to the FDA.

Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final.”

When draft documents are submitted for BARDA review, BARDA will provide feedback to Contractor within [***] of receipt.

When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA’s written concerns and/or recommendations prior to FDA submission.

Final FDA submissions shall be submitted to BARDA concurrently or no later than [***] of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within [***] after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plan’s 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 for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

Contractor shall notify CO and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit/audit if the FDA does not provide advanced notice.

Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA, Subcontractor, or third party.

Within [***] of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA such as email exchange or telephone conversations in written form and submit to BARDA. Email and telephone call narratives through each month shall be submitted with the monthly report. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within [***] of correspondence.

v. Audit Reports

Within [***] of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

vi. Other Requirements/Deliverables

1. Performance Measurement Baseline Review (PMBR)

The Contractor shall submit a plan for a PMBR to occur within [***] of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

- Jointly assess areas such as the Contractor's planning for complete coverage of the SOW,
- logical scheduling of the work activities, adequate resources, and identification of inherent risks
- Confirm the integrity of the Performance Measurement Baseline (PMB)
- Provide confidence in the validity of Contractor reporting
- Identify risks associated with the PMB
- Present any revised PMBs for mutual agreement
- Present an Integrated Master Project Plan
- Present the Risk Management Plan

2. Integrated Master Project Plan

The Contractor shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to the COR 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 will be used to monitor performance of the contract. Within [***] of the effective date of the contract, the Contractor shall submit a *first draft* of an updated Integrated Master Schedule in a format agreed upon by BARDA to the COR and the CO for review and comment. The Integrated Master Schedule shall be incorporated into the contract and will be used to monitor performance of the contract.

Contractor shall include the key milestones and Go/No-Go decision gates. The IMS for the period of performance will be accepted by BARDA at the PMBR. This FINAL IMS shall be due within [***] of the effective date of the contract. Updates shall be due as requested by the COR.

3. 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 [***] of contract award. Updates shall be due as requested by the COR.

4. Work Breakdown Structure

The WBS shall be discernable and consistent. The COR 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 [***] of contract award. Updates shall be due as requested by the COR.

5. Risk Mitigation Plan

The Contractor shall develop and maintain a risk mitigation plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The management plan is to be completed by the Contractor within [***] of contract award. Updates shall be included in the monthly report, or as deemed necessary by the COR.

6. Deviation Request

During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor shall submit a Deviation Report. 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.

7. Experimental Protocols

The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for approval or upon request by the COR when required.

8. 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 [***] 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.

9. Publications

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission. Reports shall be due within [***] for manuscripts and [***] for abstracts.

10. 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 [***] prior to the issuance of any potential press release.

11. 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 [***] after occurrence of an activity or incident.

12. Security Plan

If applicable, the Contractor shall submit a security plan for review and approval within [***] of contract award.

13. Quality Management System Plan

The Contractor shall submit to the COR a Quality Management System Plan for approval no later than [***] from the date of award.

C. Risk Management Plan

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 [***] of contract award. Updates to the risk management plan shall be due as requested by the COR or Alternate COR. The Risk Mitigation Matrix shall be submitted monthly with the regular technical report.

D. GO/NO-GO DECISION POINTS AND SUCCESS CRITERIA

Contractor shall provide a presentation detailing technical progress made towards completion of Go/No-Go decision gate milestones following a prescribed template provided by BARDA prior to the In Process Review (IPR).

F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents the designated Government file sharing system. The Government shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the Government prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

F.4. SUBJECT INVENTION REPORTING REQUIREMENT

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 in FAR 52.227-11 (d) (2), and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer, except for the following modifications: (a) Contractor automatically elects and retains ownership of any subject invention upon its being made, (b) Contractor has sole discretion to decide whether a subject invention will be rated to file ("RTF") as a patent application, (b) Contractor shall only be obligated to disclose a subject invention that is RTF, (c) any such disclosure shall occur within [***] of the RTF decision being made, (d) the disclosure shall contain the same information that Contractor personnel considered when making the RTF decision, (e) Contractor shall have no obligation to notify the Contracting Officer about any decision to allow any patent rights covering a subject invention ("Subject Patent Rights") to lapse, and (f) the utilization reports shall only apply to Subject Patent Rights. A final invention statement (see FAR 27.303 (b) (2) (ii)) shall be submitted to the Contracting Officer on the expiration date of the contract, except that this obligation shall only apply to subject inventions that are RTF.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in Section G – Contract Administration Data.

For clarity, the following paragraphs in FAR Clause 52.227-11 shall not apply: (b) (2), (d) (1), (e) (1), (e) (3), (g) and (h), as well as the obligation to disclose gross royalties under (f).

F.5. CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial and non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within [***]. The Contractor must address, in writing, all concerns (e.g. study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, the COR review shall occur before submission, pursuant to the terms set forth by Section F.2 of this contract. The Contractor shall revise their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by Section F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol. For purposes of this contract, “Execution” or “Start” of a clinical study shall mean enrollment of the first subject or patient.

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract.

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. Important information regarding performing human subject research is available at https://www.niaid.nih.gov/research/clinical-research.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer’s Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

F.6. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

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/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (Aug 1989)

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

[***]
Contract Management and Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (DHHS)
Email: [***]

1. The Contracting Officer is the only individual who can legally commit 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.

2. The Contracting Officer is the only person with the 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 work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.

3. No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, shall be considered grounds for deviation from any stipulation of this contract.

4. The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

NOTE: An unauthorized commitment is an agreement that **is not binding** solely because the Government representative who made it lacked the authority to enter into that agreement on behalf of the Government. An unauthorized commitment (UC) usually results in the receipt of goods or services on behalf of the Government by someone with apparent authority, but that lacks the authority to obligate the Government; it can be intentional or unintentional. Only a warranted contracting officer has authority to obligate government funds and contractually bind the government for supplies and services within their warrant authority.

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

The following Contracting Officer's Representative (COR) will represent the Government for this contract:

[***]
U.S. Department of Health & Human Services
Administration for Strategic Preparedness and Response (ASPR) Biomedical
Advanced Research & Development Authority (BARDA)
Phone: [***]
Email: [***]

The 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 Contracting Officer in interpreting the statement of work and any other technical performance requirements;

3. Performing technical evaluation as required;

4. Performing technical inspections and acceptances required by this contract; and

5. Assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

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

The key personnel specified in this contract are considered to be essential to work performance. At least [***] prior to 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) and qualifications of the individual proposed as a substitute 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.

G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor 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 [***] 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. The first financial report shall cover the period consisting of the first full [***] following the date of the contract, in addition to any fractional part of [***] . Thereafter, reports will be on a [***].

c. 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.

d. 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,”.

e. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

f. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent to the following points of contact: [***], Phone: [***], Email: [***]

g. The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than [***]) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1, which states;

Limitation of Cost (Apr 1984)

The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government
more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government’s share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government’s and the Contractor’s share of the cost.
The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—
The costs the Contractor expects to incur under this contract in the next [***], when added to all costs previously incurred, will exceed [***] of the estimated cost specified in the Schedule; or
The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.
As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.
Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—
The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.
No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract’s estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.
If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.
Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.
If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

h. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Jan 2017).

i. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over **[***]**.
5. 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.
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over **[***]**.
10. Indirect rate (i.e. G&A, M&S etc…) - Cite rate and amount.
11. Total Cost

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations.

Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. INVOICE SUBMISSION

(a) The Contractor shall submit invoices electronically in accordance with HHSAR 352.232-71. As prescribed in HHSAR 332.7003, use the following clause:

Electronic Submission of Payment Requests

(a) Definitions. As used in this clause—

(1) “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.

(End of Clause)

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 [***] of the contract award for new contracts or date of modification for existing contracts.

o Registration emails are sent via email from [***]. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to [***] or phone [***].
o 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 [***] of receipt of the first email, contains a temporary password. You must log in with the temporary password within [***].

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.

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

(i) The contractor shall submit invoices under this contract once per month. For indefinite delivery vehicles, separate invoices must be submitted for each order.
(ii) Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.
(iii) Invoices must include the Unique Entity Identifier (UEI) from System of Award Management (SAM) of the Contractor.
(iv) 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).
(v) 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, 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 Indirect Costs)- 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 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:

1. 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).
2. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
3. 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).
4. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.7. INDIRECT COST RATES

a. The following provisional rates established under the most recent Indirect Cost Negotiation Agreement between the Contractor and its cognizant audit agency, national Institutes of Health-Division of Financial Advisory Services (NIH-DFAS), are incorporated into this contract and will be utilized for billing purposes pending the establishment of updated provisional rates or final indirect cost rates for any period as determined by NIH-DFAS, the Contractor shall be reimbursed for allowable indirect costs at the following rate(s):

b. The Contractor shall be reimbursed for allowable indirect costs at the rates identified in the Advance Understandings in Article B.6 for Option Periods 1 and 2.

c. The provisions of FAR 42.704 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 total amount of the federal share of the amount awarded for the specific base or option, when new provisional rates are established by the cognizant agency, Gritstone will utilize those rates for the award, a budget modification will not be necessary. Provisional and final rate letters shall be provided to the Contracting Officer by the Contractor upon their immediate receipt.

d. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final approved indirect cost rate letter to the contracting officer and the cognizant auditor within the [***] period following the end of each of its fiscal years or after the letter is received, 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.

G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted [***] to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment

by completing the registration form that can be obtained at the following address:

https://www.cpars.gov

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required [***] time frame.

CPARS Point of Contact for Gritstone:

[***] , Phone: [***], Email: [***]

G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

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

G.10. 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.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The Contractor, depending upon the nature of the work, is responsible for following the provisions below in conducting its own work under this contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed down as applicable.

H.1. CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer’s Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within [***]. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, the COR review shall occur before submission, pursuant to the terms set forth by Article F.2 of this contract. The Contractor shall revise their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by Article F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol. For purposes of this contract, "Execution" or "Start" of a clinical study shall mean enrollment of the first subject or patient.

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. 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. Important information regarding performing human subject research is available at https://www.niaid.nih.gov/research/clinical-research.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. Non-Clinical Terms of Award

a. These Non-Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve non- clinical research and Safety and Monitoring Issues.

i. PHS Policy on Humane Care and use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW) federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol.

They must also provide BARDA initial and annual documentation of continuing review and approval and federal wide

assurance number.

The Contractor must ensure that the application, as well as all protocols, are reviewed by the performing institution's IACUC.

To help ensure the safety of animals used in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).
Termination or temporary suspension of the study(ies) for regulatory issues.
Termination or temporary suspension of the protocol.
Any change that is made in the specific IACUC approval for the indicated study(ies).
Any other problems or issues that could affect the scientific integrity of the study(ies), i.e., fraud, misrepresentation, misappropriation of funds, etc.

Contractor must notify BARDA of any of the above changes within [***] from the time the Contractor becomes aware of such changes by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Non-Clinical Data and Safety Monitoring Requirements.

BARDA strongly recommends continued safety monitoring for all non-clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. Contractor should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non- clinical studies. In preparation for clinical trials of licensed or not yet licensed products, it is imperative that BARDA- sponsored studies of any type measure the risk and safety parameters that are elicited and provide a safety profile from the studies for future human risk assessment.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy subject for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

BARDA will work with the Contractor on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CRO's as BARDA deems necessary.

b. BARDA Review Process before Non-Clinical study Execution Begins

BARDA is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA-funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and comment by BARDA:

IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.
For non-pivotal mouse studies, the Contractor will provide an annual animal care and use protocol.
Documentation of IACUC approval, including OLAW federal wide number, IACUC registration number, and IACUC name.
Contractor should reduce the number of animals required for a study using power of statistics.
Plans for the management of side effects, rules for interventions and euthanasia criteria.
Procedures for assessing and collecting safety data were appropriate.
If a study is contracted through Contract Research Organizations (CROs), work orders and service agreements the Contractor shall assure an integrated safety documentation plan is in place for the study site, pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).
Documentation that the Contractor and all required staff responsible for the conduct of the research have received training in the protection and handling of animals, or that the CRO has the required documentation.
Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer in accordance with the contract.
Provide justification for whether studies require good laboratory practice (GLP) conditions.
Provide justification for whether studies will be classified as non-pivotal or pivotal studies.

Documentation of each of the above items shall be submitted to BARDA for evaluation and comment in conjunction with the protocol. Execution of non-clinical studies requires written authorization from BARDA in accordance with this section of the contract.

c. References

Public Health Service Policy on Humane Care and Use of Laboratory Animals: http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf

USDA Animal Welfare Act: https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa

2. Clinical Terms of Award

These Clinical Terms of Award detail an agreement between the Government and the Contractor; they apply to all grants and contracts that involve clinical research.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

a. Safety and Monitoring Issues

1. Institutional Review Board or Independent Ethics Committee Approval

Within [***] of award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance 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 BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols is reviewed by their IRB or IEC.

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

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

The Contractor must notify the COR and CO of any of the above changes within [***] by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

2. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial 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 be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer 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.

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.
Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.
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. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy.

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 COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with the CO and COR.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within [***] of reviews or meetings.

3. BARDA Protocol Review Proce1ss Before Patient Enrollment Begins

The COR 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 ensure the following (as applicable) are in place at the participating institution(s), prior to the first participant accrual or enrollment:

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.
Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.
Plans for the management of side effects.
Procedures for assessing and reporting adverse events.
Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the COR) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from the COR in accordance with this Section of this contract.

4. Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IDE, the Contractor must provide BARDA with the name and institution of the IDE sponsor, the date the or IDE was filed with FDA, the FDA or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty [***] from FDA receipt of an initial or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

5. Required Time-Sensitive Notification

Under an 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 Contracting Officer's Representative (COR) as follows:

a. 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 COR within [***] of FDA notification.

b. Expedited safety reports: Sent to the COR concurrently with the report to FDA.

c. Other adverse events documented during the course of the trial should be included in the annual IDE report and

reported to BARDA annually.

In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within [***] by email or fax, followed within [***] by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

d. Safety reporting for research not performed under an IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IDE must be made jointly by the COR and the Contractor.

H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

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 federal wide 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' FW' via designation as agents of the institution of via individual investigator agreements (see OHRP website at: http//:www.hhs.gov/ohrp/policy/guidanceonalternativeofwa.pdf).

d. If at any time during the performance of this contract, 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.

H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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 Federal, 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.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP- approved Assurances, whether domestic or foreign, and compliance must be

ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self- designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42

U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

H.5. 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 should 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 e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector
General Department of Health and Human Services TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.6. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.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.7. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right, subject to FAR 52.227-14, FAR 52.227-14 Alt II, and HHSAR 352.224-71, to review any other data determined by DHHS 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.8. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies.

Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

H.9. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant

facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, and that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within [***]. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.10. NEEDLE DISTRIBUTION

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

H.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.12. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (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 or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 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 or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.14. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to such documentation and data generated under this contract in which it has unlimited rights. For clarity, in situations where Contractor obtains image data that has been exported to DICOM files containing such image data as both (i) bitmapped (scan-converted) images in public tags and (ii) as raw (non-scan converted) images in private tags, Contractor shall have no obligation to provide the Government with access to the raw images or to any annotations that Contractor may apply to such image data. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 15 business days of receipt of request. The Government shall acquire unlimited rights in such data as outlined in accordance with FAR Subpart 27.4 and FAR Clause 52.227- 14.

H.15. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in

performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.16. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least [***] advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in Section I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

(2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than [***] for manuscripts and [***] for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

“This project has been funded 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; Biomedical Advanced Research and Development Authority, under Contract No. 75A50123C00062

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR, CO, and [***] has received an advance copy of any press release related to the contract not less than [***] prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for 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 Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50123C00062

H.17. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive- legislative relationships, the Contractor shall not use any HHS contract funds for:

a. Publicity or propaganda purposes;

b. The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

c. Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

d. The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

H.18. PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1-part5b

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09- 25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

H.19. 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 CO 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 and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14. 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 should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.20. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

H.21. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under 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. 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 COR and CO within [***] of report completion.

H.22. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with [***] 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 [***] of the audit.

COR and CO will review the report and provide a response to the Contractor with [***] .

Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.23. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

“(3) Definition of unauthorized alien – As used in this Section, the term ‘unauthorized alien’ with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General.”

H.24. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

Within [***] of activity or incident or within [***] for a security related activity or incident, Contractor must notify BARDA.

Additional updates due to COR and CO within [***] of additional developments.

Contractor shall submit within [***] a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within [***] .

H.25. DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical sections for which the contractor can assert a copyright under FAR Clause 52.227- 14 I or information shared under a Confidential Disclosure Agreement held by the Contractor, no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical Section, the contractor shall provide BARDA, through the COR, with a minimum of [***] to review the Section prior to publication.

H.26. 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/cgi- bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61) 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/regulations.html

H.27. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP) will be the standard to be applied for clinical manufacturing, processing, packaging, storage, and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have [***] from the time such material failure is identified to cure such material failure. If, within the [***] period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.28. 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 [***] prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least [***] prior to the IPR.

H.29. HUMAN SUBJECTS

The Contractor shall submit all human clinical protocols and informed consent documents to BARDA for review and comment prior to submission to another entity.

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

H.30. SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, 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.31. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 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:

   i. The creation of a human embryo or embryos for research purposes; or
   ii. 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.

H.32. 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.

H.33. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor 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 principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

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

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken

   to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within [***] of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular 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 Contractor has not managed, reduced, or eliminated the conflict of interest. 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 conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.34. [***]

[***]

H.35. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b)

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.36. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

To the extent applicable to the work performed by the Contractor under this Contract, this contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text.

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following 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. The full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Cost-Reimbursement Research and Development Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause	Date	Clause Title
52.202-1	Jun 2020	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Jun 2020	Restrictions on Subcontractor Sales to the Government
52.203-7	Jun 2020	Anti-Kickback Procedures
52.203-8	May 2014	Cancellation, Recission, and Recovery of Funds of Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
52.203-13	Jun 2020	Contractor Code of Business Ethics and Conduct
52.204-14	Jun 2020	Display of Hotline Poster(s)
52.203-17	Jun 2020	Contractor Employee Whistleblower Rights and Requirement
52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
52.204-4	May 2011	Printed or Copied Double-Sided on Post Consumer Fiber Content Paper
52.204-7	Oct 2018	System for Award Management
52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Oct 2018	System for Award Management Maintenance
52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
52.204-23	Nov 2021	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
52.204-25	Nov 2021	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Service or Equipment
52.209-6	Nov 2021	Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
52.210-1	Jun 2020	Market Research
52.215-2	Jun 2020	Audit and Records-Negotiation
52.211-5	Aug 2000	Material Requirements
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format

52.215-14	Jun 2020	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-16	June 2003	Facilities Capital Cost of Money
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
52.215-21	Nov 2021	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
52.215-23	Jun 2020	Limitations on Pass-Through Charges
52.216-7	Aug 2018	Allowable Cost and Payment
52.216-12	Apr 1984	Cost-Sharing Contract-No Fee.
52.216-21	Oct 1995	Requirements
52.216-26	Dec 2002	Payments of Allowable Costs Before Definitization
52.219-8	Oct 2018	Utilization of Small Business Concerns
52.219-28	Nov 2020	Post-Award Small Business Program Representation
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
52.222-26	Sept 2016	Equal Opportunity
52.222-35	Jun 2020	Equal Opportunity for Veterans
52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
52.222-37	Jun 2020	Employment Reports on Veterans
52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
52.222-50	Nov 2021	Combating Trafficking in Persons
52.222-54	Nov 2021	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Jun 2020	Encouraging Contractor Policy to Ban Text Messaging While Driving
52.225-1	Nov 2021	Buy American Act--Supplies
52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
52.227-1	Jun 2020	Authorization and Consent, Alternate 1 (APR 1984)
52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights – Ownership by the Contractor
52.227-14	May 2014	Rights in Data – General
52.227-14 Alt. II	Dec 2007	Rights in Data – General – Limited Rights Notice
52.227-16	June 1987	Additional Data Requirements
52.228-7	Mar 1996	Insurance – Liability to Third Persons
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jan 2017	Prompt Payment

52.232-33	Oct 2018	Payment by Electronic Funds Transfer–System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.232-40	Nov 2021	Providing Accelerated Payments to Small Business Subcontractors
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.239-1	Aug 1996	Privacy or Security Safeguards
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1984	Changes – Cost-Reimbursement Alternate V (Apr 1984)
52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
52.244-5	Dec 1996	Competition in Subcontracting
52.245-1	Jan 2017	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-8	May 2001	Inspection of Research and Development—Cost Reimbursement
52.246-9	Apr 1984	Inspection of Research and Development (Short Form)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) 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	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.222-70	Dec 2015	Contractor 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	Jan 2006	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary rate limitation
HHSAR	352.232-71	Feb 2022	Electronic Submission of Payment Requests
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-73	Dec 2015	Electronic Information and Technology Accessibility Notice

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6-months. The Contracting Officer may exercise the option by written notice to the Contractor before the contract expires.

(End of clause)

52.217-9 Option to Extend the Term of the Contract.

(a) The Government may extend the term of this Contract by notice to the Contractor within 30 days of the date the Contract expires; provided that the government gives the Contractor a preliminary notice of its intent to extend at least 60 days before the Contract expires. The preliminary notice does not commit the government to an extension.
(b) If the government exercises this option, the extended Contract shall be considered to include this option clause.
(c) The total duration of this Contract, including base period and the exercise of any options under this clause, shall not exceed **5-years**.

(End of clause)

FAR Clause 52.219-28, Post-Award Small Business Program Representation (Mar 2020)

a. *Definitions* As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is “not dominant in its field of operation” when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall re-represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of this re- representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards.

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

(1) The Contractor represents that it *FORMCHECKBOX* is, *FORMCHECKBOX* is not a small business concern under NAICS Code _____ assigned to contract number_____.

(2) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause*.] The Contractor represents that it *FORMCHECKBOX* is, *FORMCHECKBOX* is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause.*] The Contractor represents that it *FORMCHECKBOX* is, *FORMCHECKBOX* is not a women-owned small business concern.

(i) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the Contractor represented itself as a women-owned small business concern in paragraph (h)(3) of this clause.] The Contractor represents that—It *FORMCHECKBOX* is, *FORMCHECKBOX* is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It *FORMCHECKBOX* is, *FORMCHECKBOX* is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (h)(4)(i) of this clause is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. *[The Contractor shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.]* Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(4) Economically disadvantaged women-owned small business (EDWOSB) concern.[Complete only if the Contractor represented itself as a women-owned small business concern eligible under the WOSB Program in (h)(4) of this clause.] The Contractor represents that—

(i) It *FORMCHECKBOX* is, *FORMCHECKBOX* is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It *FORMCHECKBOX* is, *FORMCHECKBOX* is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (h)(5)(i) of this clause is accurate for each EDWOSB concern participating in the joint venture. [The Contractor shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture:

_____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(5) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause.*] The Contractor represents that it *FORMCHECKBOX* is, *FORMCHECKBOX* is not a veteran- owned small business concern.

(6) [*Complete only if the Contractor represented itself as a veteran-owned small business concern in paragraph (h)(6) of this clause.*] The Contractor represents that it *FORMCHECKBOX* is, *FORMCHECKBOX* is not a service-disabled veteran-owned small business concern.

(7) [*Complete only if the Contractor represented itself as a small business concern in paragraph (h)(1) of this clause.*] The Contractor represents that—

(i) It *FORMCHECKBOX* is, *FORMCHECKBOX* is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR part 126; and

(ii) It *FORMCHECKBOX* is, *FORMCHECKBOX* is not a HUBZone joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (h)(8)(i) of this clause is accurate for each HUBZone small business concern participating in the HUBZone joint venture. *[The Contractor shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: .]* Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

[*Contractor to sign and date and insert authorized signer's name and title.*]

(End of clause)

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--

“Covered contractor information system” means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

“Federal contract information” means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

“Information” means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

“Information system” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

“Safeguarding” means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clauses)

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.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. **Statement of Work**
2. **Invoice/Financing Request Instructions for Cost-Reimbursement Type Contracts,**

Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Type Contracts.

3. **Sample Invoice**
4. **Financial Report of Individual Project/Contract**
5. **Instructions for Completing Financial Report of Individual Project/Contract**
6. **Inclusion Enrollment Report**

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01)

7. **Research Patient Care Costs**
8. **BARDA Government Property Contractor Audit Form**

ATTACHMENT 1

Statement of Work
September 26, 2023

[***]

ATTACHMENT 2

INVOICE/FINANCING REQUEST INSTRUCTIONS –

FOR COST-REIMBURSEMENT TYPE CONTRACTS

[***]

ATTACHMENT 3 - SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT

[***]

ATTACHMENT 4

[***]

ATTACHMENT 5
INSTRUCTIONS FOR COMPLETING
“FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT”

[***]

ATTACHMENT 6

INCLUSION ENROLLMENT REPORT

[***]

ATTACHMENT 7 –

RESEARCH PATIENT CARE COSTS

[***]

ATTACHMENT 8

BARDA GOVERNMENT PROPERTY CONTRACTOR AUDIT FORM

[***]

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

NONEXCLUSIVE LICENSE AND DEVELOPMENT AGREEMENT

by and between GRITSTONE ONCOLOGY, INC.

on the one hand, and

GENEVANT SCIENCES GMBH

on the other hand

Dated as of January 15, 2021

NONEXCLUSIVE LICENSE AGREEMENT

This NONEXCLUSIVE LICENSE AND DEVELOPMENT AGREEMENT (this "Agreement") is entered into as of January 15, 2021 (the "Effective Date"), by and between (a) Gritstone Oncology, Inc., a Delaware corporation having a place of business at 5959 Horton Street, Suite 300, Emeryville, California 94608, USA ("Gritstone"), on the one hand, and (b) Genevant Sciences GmbH, a limited liability company organized and existing under the laws of Switzerland, having an address of Viaduktstrasse 8, 4051 Basel, Switzerland ("Genevant"), on the other hand. Capitalized terms when used in this Agreement have the meanings set forth in Article I.

WHEREAS Genevant has expertise and intellectual property relating to, among other things, LNP (as defined below) formulations for delivery of nucleic acid (such as ribonucleic acid) and methods for manufacturing LNPs;

WHEREAS Gritstone has expertise and intellectual property relating to developing pharmaceutical products and methods based on the (i) identification and selection of disease- associated antigens to induce T cells or B cells by vaccination, (ii) therapeutic vaccine platforms including [***] (as defined below) and [***] (as defined below), (iii) research and GMP (as defined below) biomanufacturing capabilities and (iv) related technology;

WHEREAS Gritstone wishes to apply Genevant's intellectual property to Develop and Commercialize Licensed Products in the Field in the Territory (each such term as defined below); and

WHEREAS Genevant desires to grant Gritstone certain nonexclusive (sub)licenses to its intellectual property upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and other good and valuable consideration, the receipt of which is hereby acknowledged, Gritstone and Genevant enter into this Agreement effective as of the Effective Date:

ARTICLE I – DEFINITIONS

1.1General. When used in this Agreement, each of the following terms, whether used in the singular or plural, shall have the meanings set forth in this Article I.

"Affiliate" means, with respect to: (a) a Person (other than Genevant), any corporation, company, partnership, joint venture or firm that controls, is controlled by, or is under common control with such Person; or (b) Genevant, each of Genevant Sciences Ltd. And each of its direct and indirect wholly owned subsidiaries. For purposes of the foregoing sentence, "control" means
(a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, or (b) in the case of noncorporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such noncorporate entities.

"Agreement" has the meaning set forth in the introductory paragraph.

"Agreement Activities" has the meaning set forth in Section 6.1(a)(iv).

"Alliance Manager" has the meaning set forth in Section 3.1(f).

"Applicable Laws" means all applicable laws, statutes, rules, regulations, guidelines, guidances, ordinances, orders, decrees, writs, judicial or administrative decisions and the like of any nation or government, any state or other political subdivision thereof, any entity exercising executive, judicial, regulatory or administrative functions of or pertaining to government (including any Governmental Authority), any tribunal or arbitrator of competent jurisdiction, and any trade organization whose regulations have the force of law.

"Boost" means a vaccine administered subsequent to administration of Prime vaccine. "Business Day" means any day that is not a Saturday, a Sunday, or other day that is a public holiday in Basel, Switzerland, a provincial or national holiday in Vancouver, British Columbia, or a state or federal holiday in the State of New York.

"Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

"Calendar Year" means a period of twelve (12) consecutive calendar months ending on December 31.

"[***]" means [***].

"Challenge" has the meaning set forth in Section 9.6.

"Challenge Notice" has the meaning set forth in Section 9.6.

"Change of Control" means, with respect to: (a) Gritstone, the occurrence of any of the following: (i) Gritstone consummates a merger, consolidation, stock sale or other similar transaction or series of transactions with anotherPerson pursuant to which: (A) the individuals and entities that were the beneficial owners of the outstanding voting securities of Gritstone immediately prior to such transaction do not beneficially own, directly or indirectly, more than fifty percent (50%) of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors or similar governing persons of the corporation or other entity resulting from such transaction("Successor") in substantially the same proportions as their ownership immediately prior to such transaction of such outstanding voting securities, or (B) less than fifty percent (50%) of the members of the Board of Directors or similar governing body of the Successor were members of the Board of Directors of Gritstone at the time of the execution of the initial agreement for such transaction; provided, however, that a stock sale to underwriters of a public offering of Gritstone's capital stock shall not constitute a Change of Control; or (ii) Gritstone enters into a sale or transfer of all or substantially all of its assets relating to this Agreement, other than to a Person that is an Affiliate of Gritstone prior to such transaction or series of transactions; and (b) Genevant, the occurrence of any of the following: (i) Genevant Parent consummates a merger, consolidation, stock sale or other similar transaction or series of transactions with another Person pursuant to which: (A) the individuals and entities that were the

beneficial owners of the outstanding voting securities of Genevant Parent immediately prior to such transaction do not beneficially own, directly or indirectly, more than fifty percent (50%) of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors or similar governing persons of the Successor in substantially the same proportions as their ownership immediately prior to such transaction of such outstanding voting securities, or (B) less than fifty percent (50%) of themembers of the Board of Directors or similar governing body of the Successor were members of the Board of Directors of Genevant Parent at the time of the execution of the initial agreement for such transaction; provided, however, that in no event shall the issuance of equity (or securities exchangeable or exercisable for or convertible into equity) ofGenevant Parent constitute a Change of Control; or (ii) Genevant enters into a sale or transfer of all or substantially allof its assets relating to this Agreement, other than to a Person that is an Affiliate of Genevant prior to such transaction or series of transactions.

"CMC" means chemistry, manufacturing, and controls, or Pharmaceutical Quality/CMC, as such terms are defined by the regulations of the applicable Regulatory Authority, including as required for Module 3 per International Conference on Harmonisation M4Q.

"CMO" means a Third Party contract manufacturing organization. "Collaboration Infringement" has the meaning set forth in Section 6.3(a).

"Commercialize" or "Commercialization" means any and all activities directed to marketing, promoting, distributing, importing, having imported, exporting, having exported, selling and having sold biologic or pharmaceutical products, including, subject to the terms of this Agreement, having Third Parties conduct such activities on behalf of the Person receiving the rights to Commercialize; provided that Manufacturing is not Commercializing.

"Commercial Milestone" has the meaning set forth in Section 4.4(a). "Commercial Milestone Payment" has the meaning set forth in Section 4.4(a).

"Commercially Reasonable Efforts" means, with respect to any particular activity or activities, the efforts and resources that would reasonably be used (including the promptness with which such efforts and resources would be applied) by a similarly situated company within the biopharmaceutical industry to execute such activity or activities in respect of a biologic or pharmaceutical product of similar market and profit potential and at a similar stage in development or product life as compared to the Product to which such activity or activities applies, taking into account, as applicable, its present and future market and commercial potential (including competitive market conditions, patent coverage, regulatory exclusivity, the size of the particular market in the applicable country for the relevant indication, actual and projected Development, Manufacturing and Commercialization costs, any issues regarding the ability to Manufacture or have Manufactured the Product; the likelihood of obtaining regulatory approvals and timing thereof; and the profitability of the relevant product or service in light of existing and anticipated competitive products and services, as well as pricing and reimbursement considerations) and all other relevant factors, including commercial, technical, legal, scientific, regulatory, or medical factors, including such Product's efficacy, safety, stability, existing and anticipated approved labeling, and post-approval requirements, in each case in the applicable country, [***]. To the extent that the performance of a Party's obligations hereunder is adversely affected by the other

Party's failure to perform its obligations hereunder, the impact of such other Party's performance failure will be taken into account in determining whether such first Party has used its Commercially Reasonable Efforts to perform the affected obligations.

"Confidential Information" means all confidential information and confidential materials, patentable or otherwise, of a Party disclosed by or on behalf of such Party to the other Party before, on or after the Effective Date in connection with the discussions and negotiations pertaining to, or in the course of performing, this Agreement, including chemical composition of a formulation in LNPs, chemical substances, equipment, data, reports, Know-How, sources of supply, patent positioning, business plans, and also the proprietary and confidential information of Third Parties in possession of such Party under an obligation of confidentiality, whether or not related to making, using or selling a Product.

"Control," "Controls" or "Controlled by" means, with respect to intellectual property, the possession of (whether by ownership or license, other than pursuant to this Agreement) the ability to grant access to, or a license or sublicense of, such intellectual property.

"Cover," "Covers" or "Covered by" means, with respect to a product, that the making, using, selling, offering for sale or importing of such product, or the practice of a method with respect to the Manufacture or use of such product, would, but for (a) the licenses granted under this Agreement or (b) any statutory or common law research exemption, infringe a Valid Claim or a patent application (considering claims of patent applications to be issued) in the country in which such activity occurs.

"COVID mRNA Vaccine" means a product that both (a) contains an RNA that codes for one or more antigens of SARS-CoV-2 and (b) acts to stimulate the human immune system [***].

"Develop," "Developing" or "Development" means any and all activities and studies required to develop biologic or pharmaceutical products for Marketing Authorization Approval or for Commercialization, including, subject to the terms of this Agreement, having Third Parties conduct such activities and studies on behalf of the Person receiving the rights to Develop; provided that Manufacturing is not Developing.

"Development Milestone" has the meaning set forth in Section 4.3. "Development Milestone Payment" has the meaning set forth in Section 4.3. "Development Milestone Table" has the meaning set forth in Section 4.3. "Disclosing Party" means the Party that discloses its Confidential Information. "Effective Date" has the meaning set forth in the introductory paragraph. "Efficacy Failure" has the meaning set forth in Section 9.4.

"EMA" means the European Medicines Agency, a body of the European Union, or any successor agency(ies) thereof performing similar functions.

"EU" means (a) any country that is a member of the European Union as of the Effective Date and (b) the United Kingdom.

"EUA" means any form of "emergency use authorization" granted by the FDA in the United States, whether pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act or otherwise.

"EUA Achievement" means, with respect to a Product, that prior to receipt of U.S. MAA for such Product for the Field, Gritstone or any of its Affiliates or Sublicensees receives EUA for such Product for the Field; provided that, with respect to any Product for which there is EUA Achievement or U.S. MAA, no Improved Product with respect to such Product shall be deemed to have EUA Achievement unless prior thereto such Improved Product has been administered in a human clinical trial, whether alone or with any other product.

"EUA Sublicense Payment" has the meaning set forth in Section 4.3(c)(ii). "Evaluation License" has the meaning set forth in Section 2.1(b).

"Excluded Claim" means a dispute, controversy or claim that concerns (a) the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

"Executive Officer" means, with respect to (a) Gritstone, Gritstone's Chief Executive Officer or a substitute or replacement executive officer of Gritstone as to which Gritstone provides written notice to Genevant or (b) Genevant, the Chief Executive Officer of Genevant Sciences Corporation or a substitute or replacement executive officer of Genevant or an Affiliate thereof as to which Genevant provides written notice to Gritstone.

"Existing Third Party Agreements" means the [***].

"Extended Cure Period" has the meaning set forth in Section 9.2(a).

"FDA" means the Food and Drug Administration of the United States Department of Health and Human Services, or any successor agency(ies) thereof performing similar functions.

"[***]" means [***].

"Field" means the cure, treatment or prevention of the disease caused by SARS-CoV-2 and commonly referred to as COVID-19.

"First Commercial Sale" means, on a Product-by-Product and country-by-country basis, the first *bona fide* sale of such Product in such country to a nonSublicensee Third Party in an arm's

length transaction after Marketing Authorization Approval, or EUA, to market such Product in such country. Sales of a Product for registration samples, compassionate use sales, named patient use, intercompany transfers to Affiliates of a Party and the like shall not constitute a First Commercial Sale.

"FTE" means [***] hours of services per year by an employee or consultant.

"FTE Rate" means the fully burdened annualized rate established by the Parties for the services of an FTE, which, for the period beginning on the Effective Date and ending [***], is [***], subject to an annual increase beginning [***] by a percentage equal to the percentage increase in the Consumer Price Index for Canada (all items) for the [***] month period ending with [***].

"GAAP" means U.S. generally accepted accounting principles as in effect from time to time, consistently applied.

"Generic Competition" means, on a Product-by-Product and country-by-country basis, that, in a given Calendar Quarter, (a) one or more Third Parties is selling a Generic Product with respect to such Product in such country and (b) Net Sales of such Product during [***] are less than [***] of the average Net Sales of such Product in such country during [***] immediately preceding [***] in which the first Generic Product is launched in such country.

"Generic Product" means, with respect to a Product and country, any product sold in such country by a Third Party (which may be called, for example and as applicable, a "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "interchangeable product," "similar biological medicinal product," or "biosimilar product") that relied in whole or in part on the Marketing Authorization Approval for such Product as a basis for approval (or on any data submitted to the applicable Regulatory Authority in connection with the process to obtain such Marketing Authorization Approval), but excluding products licensed (or products with respect to which intellectual property is or has been licensed) by Gritstone or any of its Affiliates to such Third Party in such country.

"Genevant" has the meaning set forth in the introductory paragraph.

"[***]" means [***].

"Genevant Background IP" means any and all Genevant Know-How or Genevant Patents Controlled by Genevant or its Affiliates as of the Effective Date.

"Genevant Indemnitees" has the meaning set forth in Section 8.2. "Genevant IP" has the meaning set forth in Section 6.1(a)(iv).

"Genevant Know-How" means any Know-How Controlled by Genevant or any of its Affiliates at the Effective Date or from time to time during the Term to the extent that it relates to LNPs, including: (a) the composition of matter of LNPs; (b) the method of use of LNPs; (c) LNP formulations for delivery of RNA; (d) the method of manufacturing LNPs, including the sourcing of components, assembly, or operation of LNP formulation instrumentation and reagents; or (e) the physical characteristics of LNPs, including the lipid or nonlipid components of LNPs (e.g., cationic lipid, PEG lipids, neutral lipids), particle morphology (e.g., electron dense or nonlamellar structure), and lipid ratios (e.g., molar ratios of the components). For clarity, no Genevant Patent is Genevant Know-How.

"Genevant LNP" means an LNP that is Covered by at least one (1) Genevant Patent or incorporates Genevant Know-How.

"Genevant Outside Foreground IP" means any and all Genevant Know-How or Genevant Patents created by Genevant or its Affiliates after the Effective Date other than in the performance of Agreement Activities.

"Genevant Parent" means Genevant Sciences Ltd., a Bermuda limited company. "Genevant Patent" means any Patent Controlled by Genevant or any of its Affiliates as of the Effective Date or at any time during the Term to the extent that it includes one or more claims that Cover LNPs, including: [***].

"Genevant Patent Infringement" has the meaning set forth in Section 6.3(b). "Genevant Sole IP" has the meaning set forth in Section 6.1(e)(ii).

"Good Laboratory Practices" or "GLP" means the regulations set forth in 21 C.F.R. Part 58 and the requirements expressed or implied thereunder imposed by the FDA and (as applicable) any comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the International Conference on Harmonization.

"Good Manufacturing Practices" or "GMP" means the regulations set forth in 21 C.F.R. Parts 210–211, 820 and 21 C.F.R. Subchapter C (Drugs), Quality System Regulations and the requirements thereunder imposed by the FDA, and any comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the International Conference on Harmonization.

"Governmental Authority" means any United States or supra-national, foreign, federal, state, local, provincial, or municipal government, governmental, regulatory or administrative authority, agency, body, branch, bureau, instrumentality or commission or any court, tribunal, or judicial or arbitral body having relevant jurisdiction over a subject matter, including any Regulatory Authority.

"Gritstone" has the meaning set forth in the introductory paragraph.

"Gritstone-Arbutus Agreement" means the License Agreement by and between Gritstone, on the one hand, and Arbutus Biopharma Corporation and Protiva Biotherapeutics Inc., on the other hand, dated as of October 16, 2017, as amended on July 20, 2018.

"Gritstone Background IP" means any and all Intellectual Property (including Payload IP) Controlled by Gritstone or any of its Affiliates as of the Effective Date that relates to any vaccination, [***], epitope prediction or identification, or vectors used in connection with the foregoing.

"Gritstone Indemnitees" has the meaning set forth in Section 8.1. "Gritstone IP" has the meaning set forth in Section 6.1(c).

"Gritstone Outside Foreground IP" means any and all Intellectual Property created by Gritstone or any of its Affiliates after the Effective Date other than in the performance of Agreement Activities.

"[***]" means [***].

"Gritstone Sole IP" has the meaning set forth in Section 6.1(e)(iii).

"Heterologous System" means [***].

"Homologous System" means [***]. For example, [***].

"Improved Product" means, [***].

"IND" or "Investigational New Drug Application" shall mean an investigational new drug application, or an analogous application required by a Governmental Authority anywhere in the world, required in order to conduct an initial clinical trial for the experimental form of a pharmaceutical product. For clarity, for purposes of this Agreement, a single IND encompasses both: (a) multiple IND numbers issued by the Governmental Authority when the subsequent IND numbers are issued for administrative convenience or other administrative purposes, and (b) all applications in jurisdictions outside the United States that involve substantially similar information as typically submitted in an IND submitted to the FDA.

"Indemnified Party" has the meaning set forth in Section 8.3. "Indemnifying Party" has the meaning set forth in Section 8.3. "Infringement Action" has the meaning set forth in Section 6.3(c).

"[***]" means [***].

"[***]" means [***].

"[***]" means [***].

"Insolvent Party" has the meaning set forth in Section 9.7(a). "Intellectual Property" means Patents and Know-How. "JAMS Rules" has the meaning set forth in Section 10.7(c). "Joint IP" has the meaning set forth in Section 6.1(e)(iv). "Joint Patent" means any Patent that Covers Joint IP.
"JSC" has the meaning set forth in Section 3.1(a).

"Know-How" means biological materials and other tangible materials, information, data, inventions, practices, methods, methodologies, protocols, formulas, formulations, oligonucleotide sequences, knowledge, trade secrets, processes, assays, skills, techniques and results of experimentation and testing, patentable or otherwise.

"Knowledge Parties" means [***].

"Licensed Intellectual Property" means any and all Genevant Patents and Genevant Know-How.

"LNP" means lipid nanoparticle (excluding encapsulated drug, such as Payload(s)), components of lipid nanoparticles, and methods of manufacturing lipid nanoparticles, including (i) the composition of matter of lipid nanoparticle(s), (ii) the physical characteristics of lipid nanoparticle(s), including the lipid or nonlipid components of lipid nanoparticle(s) or (iii) lipid ratios (i.e., ratios of the lipid components within a formulation). For clarity, "LNPs" means one or more LNP, and "LNP" does not include Payload(s).

"[***]" means [***].

"Losses" has the meaning set forth in Section 8.1.

"Major Markets" means [***].

"Manufacture" or "Manufacturing" means, with respect to a Product or its components (including LNPs), all activities associated with the production, manufacture and processing of such Product, and the filling, finishing, packaging, labeling, shipping, and storage of such product, including formulation process scale-up for GLP toxicology and clinical study use, aseptic fill and finish, stability testing, analytical development, quality assurance and quality control, and the production of the bulk finished dosage form of such Product in compliance with GMP. For clarity, Manufacture includes the manufacture of LNPs for the sole purpose of the formulation and manufacture of Products.

"Manufacturing Know-How" means, with respect to a Product or its components (including LNPs) (a) all Know-How used by Genevant and its Affiliates (or their respective

contractors) necessary to Manufacture such Product (including manufacturing, process engineering, SOPs, documents relating to the production process, data, information and results (e.g., batch records, deviation reports, in process tracking and trending data, analytical testing, development and validation reports, vendor audits, etc.) relating to the production process); and

(b) any other Know-How that is necessary to Manufacture such Product in compliance with GMP, including the identity, amounts and assurance quality of ingredients, the manufacturing processes and controls, specifications, technology, inventions, assays, quality control and testing procedures, and batch records.

"Manufacturing Facility" has the meaning set forth in Section 3.4(a).

"Marketing Authorization Approval" or "MAA" means, with respect to any country or region, any registration, license, approval or authorization from any Regulatory Authority required to market a Product in such country or region, including any pricing or reimbursement approval required by Applicable Laws to obtain such registration, license, approval or authorization, excluding any EUA.

"Necessary Third-Party IP" means with respect to any country in the Territory and any Product, on a country-by-country basis, any issued Patent owned or controlled by a Third Party in such country that would be infringed [***] by the exploitation of Licensed Intellectual Property to Develop, Manufacture or Commercialize such Product in such country in the absence of a license. For clarity, "Necessary Third-Party IP" excludes [***].

"Net Sales" means the gross amount [***] on sales or other dispositions in the Territory of a Product during a Royalty Payment Term to Third Parties [***], less:

(a) normal and customary cash, trade, quantity or prompt settlement discounts, chargebacks, rebates, reimbursements and allowances actually allowed or granted, including to trade customers, wholesalers and other distributors, pharmacies and other retailers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government, and any other adjustments, including those granted on account of price adjustments and billing errors, and including any retroactive price reductions that are actually allowed or granted;

(b) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or *bona fide* price reductions determined by [***] in good faith, and uncollectible amounts on previously sold Products;

(c) rebates and similar payments specifically allocated to sales of Product paid for by managed care organizations, hospitals, other buying groups or any governmental or Regulatory Authority including federal or state Medicaid, Medicare or similar state program in the United States or equivalent governmental programs in any other country, other providers of health insurance coverage, health care organizations or administrators, or patient assistance or other similar programs; refunds specifically allocated to sales of the Product made in connection with revenue or cost caps agreed with such organizations or entities; compulsory payments and cash rebates specifically allocated to sales of the Product paid to a Governmental Authority pursuant to governmental regulations by reason of any national or local health insurance program or similar

program, including required chargebacks and retroactive price reductions, to the extent allowed and taken, including government levied fees as a result of healthcare reform policies (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48)), to the extent such fees are specifically allocated to sales of such Product as a percentage of [***] entire pharmaceutical or biological product sales;

(d) excise taxes, customs duties, customs levies and import fees and other taxes imposed on the sale, importation, use or distribution of the Product;

x

(e) administrative fees paid to group purchasing organizations, managed care entities or other similar types of organizations or networks participating in the distribution or sales of the Product;

(f) amounts paid or credited to customers for inventory management services;

(g) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) that is reasonably allocated to the sale of the Product;

(h) payments made for separately itemized insurance and transportation costs incurred in shipping the Product, including packaging, freight, postage, shipping, transportation, warehousing, handling and insurance charges, in each case actually allowed or paid for the delivery of Product, and any customary payments with respect to Product actually made to wholesalers or other distributors, in each case actually allowed or paid for distribution and delivery of Product, to the extent billed or recognized; and any other similar and customary deductions that are consistent with GAAP or, in the case of non-United States sales, other applicable accounting standards.

Net Sales shall be determined from books and records maintained in accordance with GAAP or other applicable accounting standards. Nothing herein shall prevent [***] from selling, distributing or invoicing any Product at a discounted price to Third Parties in connection with clinical studies, compassionate or named patient sales, or an indigent program or similar bona fide arrangements in which such party agrees to forego a normal profit margin for good faith business reasons. To the extent that [***] receives any consideration other than monies for the sale of Products, Net Sales shall include the fair market value of such consideration. For the avoidance of doubt, neither (i) the supply of a Product free of charge nor (ii) the transfer of a Product between [***] for resale shall be included in the computation of Net Sales, but, in the case of clause (ii), the subsequent resale of such Product by [***] to a Third Party shall be included within the computation of Net Sales.

If a Product is formulated, packaged or sold with one or more other active ingredients or products for a single price (a "Combination Product"), the Net Sales of the Product shall be calculated for each applicable [***] by multiplying the Net Sales (as determined without reference to this paragraph) of the Combination Product by the fraction A/(A+B), where A is the average gross selling price in the applicable country of the Product(s) when sold separately in finished form, and B is the average gross selling price in the applicable country of the other active ingredient(s) or product(s) included in the Combination Product when sold separately in finished form, in each case for the most recent period in which sales of both occurred. If the Product(s) is/are sold as part

of a Combination Product and is/are sold separately in finished form, but the other product(s) included in the Combination Product are not sold separately in finished form, the Net Sales of the Product shall be determined by multiplying the Net Sales of the Combination Product by the fraction A/C, where: A is the average gross selling price in the applicable country of the Product(s) contained in such Combination Product when sold separately, and C is the average gross selling price in the applicable country of the Combination Product. If the Product(s) is/are sold as part of a Combination Product and is/are not sold separately in finished form, but the other product(s) included in the Combination Product are sold separately in finished form, the Net Sales of the Product shall be determined by multiplying the Net Sales of the Combination Product by the fraction C-B/C, where: B is the average sale price of the other product(s) included in such Combination Product when sold separately, and C is the average sale price of the Combination Product. If, on a country-by-country basis, the Product component is not sold separately in that country, Net Sales for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction D/(D+E), where D is the fair market value of the portion of the Combination Product that contains the Product and E is the fair market value of the portion of the Combination Product containing the other active ingredient(s) included in such Combination Product, as such fair market values are determined by [***].

The foregoing analysis shall be conducted on a country-by-country basis as reasonably required to determine relative fair market values of the relevant Combination Product components.

"Notice of Dispute(s)" has the meaning set forth in Section 10.7(b).

"[***]" means any and all viruses constituting [***], including, for clarity, the following [***] and any and all species of [***] constituting any of the foregoing.

"Party" means Genevant or Gritstone, and "Parties" means Genevant and Gritstone. "Patent" means any patent (including any reissue, extension, substitution, confirmation, re-registrations, re-examination, revival, supplementary protection certificate, patents of addition, continuation, continuation-in-part, or divisional) or patent application (including any provisional application, nonprovisional patent application, continuation, continuation-in-part, divisional, PCT international applications or national phase applications), in each case whether in the United States or any foreign country.

"Payload(s)" means one or more RNA contained in a Product that is proprietary to Gritstone or its licensees or sublicensees (including any Sublicensees) and encodes [***].

"Payload IP" means Intellectual Property [***].

"Payload Material" has the meaning set forth in Section 3.3(a).

"Permitted Contractor" means a Third Party (e.g., a contractor or consultant) that performs activities for which Gritstone is responsible under this Agreement under a *bona fide* contract services arrangement; provided, however, that Gritstone shall not appoint any [***] as a Permitted Contractor without Genevant's prior written consent (which consent may be granted or withheld in Genevant's sole discretion).

"Person" means an individual, corporation, limited liability company, syndicate, association, trust, partnership, joint venture, unincorporated organization, government agency or any agency, instrumentality or political subdivision thereof, or other entity.

"Phase I Study" means a human clinical study of a Product conducted in healthy volunteers or patients under the same or substantially similar protocol or IND, as each may be amended or supplemented, in any country, that generally provides for the first introduction into humans of such Product and the primary purpose of which is obtaining data regarding any or all of safety, metabolism, pharmacokinetic properties and clinical pharmacology and, potentially, to gain early evidence on effectiveness, as described in or contemplated by U.S. 21 C.F.R. 312.21(a).

"Phase II Study" means a human clinical study (including any safety run-in to such clinical study, which for clarity shall be considered part of the same clinical study and not a separate clinical study) of a Product conducted in healthy volunteers or patients with a particular disease or condition under the same or substantially similar protocol or IND, as each may be amended or supplemented, in any country, following completion of one or more Phase I Studies of such Product and with a principal purpose of evaluating the effectiveness, safety, or acceptable dose range for such Product for a particular use, as described or contemplated by 21 C.F.R. §312.21(b).

"Phase III Study" means a human clinical study (including any safety run-in to such clinical study, which for clarity shall be considered part of the same clinical study and not a separate clinical study) of a Product that: (a) is (i) conducted in patients with a particular disease or condition in any country, (ii) conducted under the same or substantially similar protocol or IND, as each may be amended or supplemented, in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and (iii) intended to evaluate the benefit-risk relationship of such Product in a defined patient population that provides, alone or together with other clinical studies, an adequate basis of data to support a Marketing Authorization Approval (or EUA); or (b) is a human clinical study that (i) Gritstone or any of its Affiliates refers to publicly in a press release issued, or a filing with the Securities and Exchange Commission, by Gritstone or any of its Affiliates or Sublicensees, as a (or as a potential) "Phase III," "pivotal" or "registration" study or (ii) supports a Marketing Authorization Approval (or EUA), in each case (clauses (a) and (b)) even if denominated as a Phase II study.

"Prime" means the initial vaccine that precedes the Boost vaccine. "Proceeds" has the meaning set forth in Section 6.3(h).

"Product" means a COVID mRNA Vaccine (a) containing [***] and (b) where [***]; provided that Product does not include any product that can be used for treatment or prevention of a [***] in a human.

"Product IP" means (a) all Product Patents and (b) all Product-specific Know-How, including for clarity nonclinical and clinical data.

"Product Patents" means all Patents that [***].

"R&D Budget" has the meaning set forth in Section 3.2. "R&D Support Plan" has the meaning set forth in Section 3.2.

"Receiving Party" means the Party that receives Confidential Information of the other Party.

"Record Retention Period" has the meaning set forth in Section 4.7(b).

"Regulatory Authority" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of a Product under this Agreement. The term "Regulatory Authority" includes the FDA, the EMA, the European Commission and relevant national competent authorities in the EU member states.

"Research" or "Researching" means identifying, evaluating, validating and optimizing products prior to readiness to conduct pre-IND GLP toxicology studies thereon.

"RNA" means ribonucleic acid, and includes, for clarity, mRNA. "Royalty" has the meaning set forth in Section 4.5.

"Royalty Payment Term" means, on a Product-by-Product and a country-by-country basis, the term beginning on the First Commercial Sale of such Product in such country and ending on the later of (a) the date of the last to expire Valid Claim that exists in such country that would be infringed by the commercial making, using, offering for sale or selling of such Product in such country absent the license grants in this Agreement; and (b) [***] from the date of First Commercial Sale of such Product in such country.

"Safety Failure" has the meaning set forth in Section 9.4.

"SARS-CoV-2" means the coronavirus (s*evere acute respiratory syndrome coronavirus 2* of the genus *Betacoronavirus*) that is the causative agent of the disease commonly referred to as COVID-19.

"[***]" means [***].

"Specified Licenseholder" means, [***].

"Solvent Party" has the meaning set forth in Section 9.7(a). "Sublicense" has the meaning set forth in Section 2.2.

"Sublicense Event" means [***].

"Sublicense Revenue" means [***].

"Sublicensee" means a Third Party to whom Gritstone has granted a Sublicense under Section 2.2, but excluding any wholesaler or distributor based on a wholesaler or distributor arrangement for the sale of Product, or any contract research organization or manufacturer providing research, development or manufacturing services to Gritstone or any of its Affiliates or Sublicensees (even if such entity is granted a right or license to make (but not to sell) Product).

"Term" means the term described in Section 9.1. "Territory" means worldwide.

"Third Party" means any Person other than Genevant, Gritstone and their respective Affiliates.

"Third-Party Claim" has the meaning set forth in Section 8.3.

"Third-Party Financial Terms" has the meaning set forth in Section 4.9. "Third-Party License" has the meaning set forth in Section 4.9. "Upfront Payment" has the meaning set forth in Section 4.1.

"U.S. Approval Date" means, with respect to each Product, the date that U.S. Marketing Application Approval for such Product occurs.

"U.S. Bankruptcy Code" has the meaning set forth in Section 9.7(b).

"U.S. Marketing Application" means, with respect to any product, an application to commercially distribute, sell or market such product in the United States, including any of: a new drug application, supplemental new drug application, biologics license application, or supplemental biologics license application; a successor application to any of the foregoing in the United States; or a supplement or amendment to any of the foregoing. For clarity, U.S. Marketing Application expressly excludes a request or application for EUA.

"U.S. Marketing Application Approval" or "U.S. MAA" means, with respect to any product, the granting or approval by the FDA of a U.S. Marketing Application for such product. For clarity, (a) a U.S. Marketing Application Approval is also a Marketing Authorization Approval and (b) U.S. Marketing Application Approval expressly excludes EUA.

"Valid Claim" means a claim of an issued and unexpired Genevant Patent or Joint Patent, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

1.2 Interpretation.

(a) Words such as "herein," "hereinafter," "hereof" and "hereunder" refer to this Agreement as a whole and not merely to a section, paragraph or clause in which such words appear,

unless the context otherwise requires. Enumerative references to sections, paragraphs or clauses, or exhibits, without reference to an explicit agreement, document or exhibit, refer to this Agreement or exhibits attached to this Agreement, as applicable. The singular shall include the plural, and each masculine, feminine and neuter reference shall include and refer also to the others, unless the context otherwise requires. The words "include," "includes" and "including" are deemed to be followed by "without limitation" or words of similar import. Except where the context otherwise requires, the word "or" is used in the inclusive sense (and/or). All dollar amounts are expressed in U.S. dollars. References to the "knowledge" of a Party are deemed to mean the actual knowledge of any of the Knowledge Parties."

(b) This Agreement is between financially sophisticated and knowledgeable parties and is entered into by the Parties in reliance upon the economic and legal bargains contained herein. The language used in this Agreement has been negotiated by the Parties and shall be interpreted and construed in a fair and impartial manner without regard to such factors as the Party that prepared, or caused the preparation of, this Agreement or the relative bargaining power of the Parties.

ARTICLE II - LICENSE GRANTS

2.1 Nonexclusive License Grant to Gritstone.

(a) Subject to the terms and conditions in this Agreement, Genevant hereby grants to Gritstone, and Gritstone hereby accepts, a nonexclusive, sublicensable (subject to Section 2.2), transferable (subject to Section 10.4) right and license or sublicense (as the case may be) under Licensed Intellectual Property to Research, Develop, Manufacture, have Manufactured (subject to Section 3.5) and Commercialize Products for the Field in the Territory; provided that, upon consummation of a Change of Control of Gritstone, unless Genevant consents otherwise in writing, [***].

(b) Subject to Section 2.6, a nonexclusive, sublicensable (but only to Permitted Contractors), nontransferable (except in connection with a permitted assignment of this Agreement in its entirety in accordance with Section 10.4) right and license or sublicense (as the case may be) under Licensed Intellectual Property to Research potential Products in the [***] Field during the period beginning on the Effective Date and ending on [***] (the "Evaluation License"); provided that, promptly following completion of each study conducted in the practice of the Evaluation License (including the NHP Study, as defined in Section 2.6), Gritstone shall provide a summary of the results of such study in reasonable detail to Genevant solely for purposes of Genevant's internal research. For clarity but without limitation, the Evaluation License does not include the right to conduct any human clinical studies.

2.2Sublicensing. Gritstone may grant sublicenses under Licensed Intellectual Property licensed under Section 2.1 (with the right to sublicense through multiple tiers only as set forth in this Section 2.2) (each, a "Sublicense"); provided that:

(a) Gritstone shall not have the right to grant a Sublicense (and no Affiliate of Gritstone or Sublicensee shall have the right to grant a sub-Sublicense) (i) to [***] or (ii) with respect to Products that [***], in each case (clauses (i) and (ii)) without Genevant's prior written

consent (which consent may be granted or withheld in Genevant's sole discretion);

(b) except in the case of a Sublicense by Gritstone to an Affiliate, each Sublicense and sub-Sublicense shall be (x) in writing and on terms consistent with, and subject to, the terms that expressly apply to Sublicensees under this Agreement and (y) granted (i) to a Permitted Contractor or (ii) contemporaneously and in conjunction with a grant of a license under Intellectual Property Controlled by Gritstone or any of its Affiliates (other than pursuant to this Agreement) to Research, Develop, Manufacture or Commercialize [***];

(c) upon termination of this Agreement, any Sublicense shall convert into a direct license from Genevant under the terms of this Agreement; provided that the scope of the rights licensed under such direct license will be limited to the scope of the applicable Sublicense; and further provided that the applicable Sublicensee (i) is not then in breach of the applicable sublicense agreement, (ii) agrees in writing to be bound to Genevant as a licensee under the terms and conditions of this Agreement (subject to the limited scope noted in this clause (c), as applicable), and (iii) agrees in writing that in no event shall Genevant assume any obligations or liability, or be under any obligation or requirement of performance that extends beyond Genevant's obligations and liabilities under this Agreement;

(d) except in the case of a Sublicense by Gritstone to an Affiliate, Gritstone shall provide Genevant with a copy of the executed Sublicense within [***] following its execution or in the case of a sub-Sublicense, within [***] following Gritstone's receipt thereof, with such reasonable redaction as Gritstone or its Sublicensee may make; provided that such redactions do not include provisions necessary to demonstrate compliance with the requirements of this Agreement;

(e) the grant of such Sublicense shall not relieve Gritstone of its obligations under this Agreement, each of which shall continue without regard to such Sublicense; and

(f) as between Genevant and Gritstone, Gritstone shall be responsible for the compliance by such Sublicensee with any and all terms of this Agreement that expressly apply to such Sublicensees hereunder; provided that, for clarity, any act or omission by a Sublicensee in connection with this Agreement that, if committed by Gritstone would be a breach of this Agreement, shall constitute a breach of this Agreement by Gritstone.

2.3Retained Rights. Genevant expressly retains all right, title and interest not expressly granted to Gritstone under this Article II (or otherwise under this Agreement), including, for the avoidance of doubt, all rights with respect to its Licensed Intellectual Property for use in or outside of the Field. For clarity, Genevant does not grant to Gritstone under this Agreement a license under Licensed Intellectual Property or otherwise to Research, Develop, Manufacture or otherwise improve upon Genevant LNPs other than to the extent expressly provided under Section 2.1.

2.4Contractors. Subject to Section 2.2, Gritstone may utilize Permitted Contractors to perform any activities contemplated under this Agreement to be performed by Gritstone (including if applicable the work ascribed to Gritstone under any R&D Support Plan) in accordance with this Agreement; provided that Gritstone shall not share Genevant's Confidential Information with any Permitted Contractor unless Gritstone and its Permitted Contractor shall have executed a binding

agreement which contains obligations of confidentiality and nonuse, as well as invention assignment provisions, consistent with and at least as protective of Genevant's rights as the corresponding provisions of this Agreement.

2.5Cross License. During the Term, (a) without limiting Section 2.1, Genevant shall, and hereby does, grant to Gritstone a royalty-free, nonexclusive research license under Licensed Intellectual Property as necessary for Gritstone to conduct the work ascribed to Gritstone in any R&D Support Plan and (b) Gritstone shall grant to Genevant and its Affiliates a royalty-free, nonexclusive research license under intellectual property owned or controlled by Gritstone as necessary for Genevant and its Affiliates to conduct the work ascribed to Genevant in any R&D Support Plan.

2.6Termination of Evaluation License by Genevant. Genevant may terminate the Evaluation License in whole or in part by providing [***] prior written notice to Gritstone if Genevant is engaged in any good faith Third Party discussion that may reasonably be expected to lead to an exclusive license grant of Intellectual Property rights in respect of all or any portion of the [***] Field to a Third Party. Upon Gritstone's receipt of the ("Evaluation Termination Notice"), the Evaluation License will, upon the expiration of the [***] notice period, terminate. If, at any time after Gritstone's receipt of the Evaluation Termination Notice, the negotiations between Genevant and such Third Party are terminated without the consummation of such exclusive license grant, Genevant shall provide written notice to Gritstone of such termination and the Evaluation License shall again become operative. For clarity, a termination of the Evaluation License by Genevant as contemplated by this Section 2.6 shall not give rise to a termination of this Agreement, and this Agreement shall continue following such termination of the Evaluation License in full force and effect. Notwithstanding the foregoing, in the event Gritstone or any of its Affiliates [***] following the Effective Date, a termination of the Evaluation License by Genevant as contemplated by this Section 2.6 or the expiration of the Evaluation License pursuant to Section 2.1(b) shall not [***].

ARTICLE III - SCOPE OF COLLABORATION

3.1 Joint Steering Committee.

(a) If the Parties develop any R&D Support Plan in accordance with Section 3.2, then the Parties shall, within [***] of finalizing and agreeing upon such R&D Support Plan, establish a joint steering committee (the "JSC"), consisting of an equal number of members appointed by each Party, which number of members shall not exceed two (2) from each Party, to oversee the conduct of activities under any R&D Support Plan; and make any amendments thereof (which amendments may be proposed to the JSC for approval by either Party), subject to the terms set forth herein. Each Party's JSC members shall collectively have the appropriate expertise to oversee such Party's performance of its obligations under this Agreement. The initial JSC members shall be designated by each Party within [***] after the Effective Date. Each Party shall have the right, at any time and from time to time, to designate a replacement, on a permanent or temporary basis, for any or all of its previously designated members of the JSC. Ad hoc guests who are bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in Article VII may be invited to the JSC meetings.

(b) The JSC shall meet at least [***] (or more frequently as the Parties may agree) on such dates and at such times as the Parties may agree; *provided, however*, that the first meeting of the JSC must occur within [***] of the Effective Date. The Parties shall agree in advance on a written agenda for each meeting of the JSC. The regularly scheduled JSC meetings shall take place in person or telephonically, as determined by the Parties. The members of the JSC may also convene or be polled or consulted from time to time by means of telephone conference, video conference, electronic mail or correspondence and the like, as the Parties deem necessary. Minutes of any meeting of the JSC shall be promptly issued to the Parties following each meeting, and the Parties shall use diligent efforts to agree as to the specific text of such minutes within [***] of issuance.

(c) JSC Disputes.

(i)Within the JSC. All decisions within the JSC shall be made by consensus. If the JSC is unable to reach consensus on such decision, either Party may elect to submit such issue first to the Parties' Alliance Managers and, if still unresolved, to the Parties' Executive Officers, in accordance with Section 3.1(c)(ii).

(ii)Referral to Alliance Managers; Executive Officers. If a Party makes an election under Section 3.1(c)(i) to refer a matter to the Alliance Managers, the JSC shall submit in writing the respective positions of the Parties to their respective Alliance Managers. Such Alliance Managers shall use good faith efforts to promptly resolve such matter. If the Alliance Managers are unable to reach consensus on any such matter within [***] after its submission to them, such matter shall be escalated to the Parties' Executive Officers. Each Party's Alliance Manager shall submit in writing the position of the Party it represents to the Executive Officer of such Party. The Executive Officers shall use good faith efforts to promptly resolve such matter within [***] after the Alliance Managers' submission of such matter to them. If the Executive Officers are unable to reach consensus on any such matter within [***] after its submission to them, then: (A) if the matter pertains to a proposed amendment to the R&D Support Plan, then the then-current R&D Support Plan shall remain in effect; and (B) if the matter pertains to conduct of activities under the existing R&D Support Plan, then the Parties Executive Officers shall continue to use good faith efforts to promptly resolve such matter until a consensus is reached.

(d) Each Party shall be responsible for the costs of its representatives on the JSC, including all travel and related costs and expenses for its members and approved invitees to attend meetings of, and otherwise participate on, the JSC.

(e) Notwithstanding anything to the contrary herein, neither the JSC nor any member of the JSC in such capacity shall be empowered to change or waive the terms or conditions of this Agreement.

(f) Each Party shall appoint an individual (from the Party or from an Affiliate of such Party) to act as the first point of contact between the Parties with regard to questions relating to this Agreement or the overall relationship between the Parties (each an "Alliance Manager" and collectively the "Alliance Managers"). The Alliance Managers will: (i) use good faith efforts to attend meetings of the JSC; and (ii) facilitate the resolution of any issue on which the JSC is unable to reach consensus, in accordance with Section 3.1(c).

3.2R&D Support Plan. Any Research, Development, or Manufacturing plan agreed upon by the Parties (an "R&D Support Plan") shall describe (a) the activities to be performed during the period of such plan by Genevant and the applicable deliverables and projected timelines and budget ("R&D Budget") and (b) the activities that may be performed during the period of such plan by Gritstone; provided that, for clarity but without limitation, neither Party shall have any obligation to agree to an R&D Support Plan and each Party shall have the right to agree or not to agree in its sole discretion. Once prepared and agreed, if at all, each R&D Support Plan shall thereupon be deemed incorporated by reference into and to become part of this Agreement. Each R&D Support Plan, if any, will cover a period to be agreed between the Parties.

3.3 Payload Material; Performance of R&D Support Plan.

(a) Genevant shall not, and shall cause its Affiliates to not: (i) use any Payload material provided by or on behalf of Gritstone, including any information or data generated by either Party relating thereto, ("Payload Material") for any activity other than as set forth in this Agreement, including in any R&D Support Plan; (ii) transfer any Payload Material to any Person (other than a contractor performing services for Genevant for its Affiliates) without Gritstone's prior written consent; or (iii) modify, analyze, deconstruct or reverse engineer any Payload Material to determine the structure, sequence or composition of such Payload Material (including to develop any Know How or other Intellectual Property directed to or otherwise pertaining to any Payload Material, including the chemical modification of any Payload Material embodied by such Payload Material or details of any polypeptide arising from the expression of any Payload Material).

(b) Genevant shall: (i) use Commercially Reasonable Efforts to perform its responsibilities under any R&D Support Plan; (ii) perform any R&D Support Plan in good scientific manner and in compliance in all material respects with all Applicable Laws and all applicable Good Laboratory Practices and Good Manufacturing Practices, if any; and (iii) use personnel with appropriate skills and experience, and with sufficient access to appropriate equipment and facilities, to perform its responsibilities under any R&D Support Plan. Except as provided in any R&D Support Plan, Genevant shall not subcontract any of its responsibilities under such R&D Support Plan without the prior written consent of Gritstone (not to be unreasonably withheld, delayed or conditioned).

(c) Genevant shall provide Gritstone with quarterly reports and a comprehensive final report within [***] following completion of the activities for which it is responsible as set forth in any R&D Support Plan. Each report will contain a reasonably detailed summary of the results of the activities performed by Genevant and any underlying raw data.

(d) Genevant shall maintain records, in sufficient detail and in good scientific manner appropriate for patent purposes, which shall accurately reflect the work done and results achieved in the performance of any R&D Support Plan.

3.4 Technology Transfer.

(a) Subject to Section 4.2, with respect to each Product, at the reasonable request of Gritstone (taking into account technology transfers made under any other agreement between

Genevant (or its Affiliates) and Gritstone, it being understood that Gritstone will have the right to exploit any Know-How transferred to it in connection with such transfers within the scope of the license granted under Section 2.1) made no earlier than [***] (i) [***] or (ii) [***], Genevant shall, as soon as reasonably practicable thereafter (A) transfer all Manufacturing Know-How to Gritstone or a Third Party CMO designated by Gritstone and (B) support Gritstone in the establishment and validation of an alternative facility for the Manufacture of such Product (the "Manufacturing Facility"). In particular, Genevant shall:

(i)transfer to Gritstone or such CMO all tangible embodiments of all Manufacturing Know-How;

(ii)provide Gritstone or such CMO technical assistance to implement the processes for the Manufacture of such Product, including the procurement and installation of any process and analytical equipment and, at the request of Gritstone, provide additional documentation, telephone or on-site visits; provided, however, that Gritstone shall reimburse Genevant for all travel expenses reasonably incurred at the request of Gritstone; and

(iii)at the request of Gritstone, provide such on-site technical assistance necessary for the installation, startup and validation of the Manufacturing Facility and Manufacture of Product.

(b) With respect to each Product, once the technology transfer is complete pursuant to this Section 3.4, Gritstone shall assume all responsibilities for future Manufacturing of such Product and any further technical support that Genevant may provide shall be at the sole reasonable expense of Gritstone.

3.5Manufacturing and Supply. Solely if and to the extent the Parties agree after the Effective Date on manufacturing and supply terms (including compensation therefor), Genevant will: (a) be responsible for the Manufacture and supply to Gritstone of each Product (excluding the Manufacture and supply of Payloads and [***]) for preclinical use prior to the initiation of human clinical testing of such Product, including analytical testing of LNP components; and (b) provide associated manufacturing and analytical documentation. After successful transfer of an LNP formulation for a Product to Gritstone or Gritstone's CMO, Gritstone will assume responsibilities for future manufacturing of such Product; provided that Genevant will provide reasonable ongoing technical support if reasonably requested by Gritstone.

ARTICLE IV - FINANCIAL PROVISIONS

4.1Upfront Payment. In partial consideration for the rights granted to Gritstone under this Agreement, on or before [***] following the Effective Date, Gritstone shall make a one-time fully-earned, nonrefundable and noncreditable payment to Genevant in the amount of $1,500,000 (the "Upfront Payment").

4.2Payments for R&D Support Plan, Technology Transfer and Manufacture and Supply.

(a) Gritstone shall: (i) reimburse Genevant for: (A) materials utilized by Genevant or its Affiliates in the performance of any R&D Support Plan in an amount equal to [***], but in

no event to exceed [***]; (B) materials utilized by Genevant or its Affiliates in the performance of a technology transfer pursuant to Section 3.4 in an amount equal to [***]; and (C) all other reasonable out-of-pocket expenses incurred by Genevant or its Affiliates in the performance of an R&D Support Plan, a technology transfer pursuant to Section 3.4 ; and (ii) pay to Genevant for time spent by employees or consultants of Genevant or its Affiliates working on an R&D Support Plan [***] or a technology transfer pursuant to Section 3.4, an amount calculated based on the FTE Rate.

(b) Within [***], Genevant shall provide Gritstone with an invoice of reimbursable costs incurred in performance of any R&D Support Plan or a technology transfer pursuant to Section 3.4 (in each case as set forth in Section 4.2(a)), and Gritstone shall pay to Genevant any undisputed invoices within [***] of receipt thereof.

4.3Development Milestone Payments. Subject to the terms and conditions of this Agreement (including clauses (a)-(c) of this Section 4.3), Gritstone shall pay to Genevant each of the nonrefundable, noncreditable payments set forth in the table below (each a "Development Milestone Payment") upon the first achievement of the corresponding development milestone (as set forth in the table in this Section 4.3, each a "Development Milestone" and such table, the "Development Milestone Table") by [***].

Development Milestone	**Development Milestone Payment**			
[***]	[***]			
[***]	[***]			
[***]	[***]			
[***]	[***]			
[***]	[***]			
[***]	[***]			
	[***]			
	[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]	[***]

For clarity: [***]. Gritstone shall provide written notice to Genevant of the occurrence of each Development Milestone within [***] of its occurrence and pay the corresponding Development Milestone Payment to Genevant within [***] after delivery of an invoice from Genevant therefor.

Notwithstanding the foregoing:

(a) with respect to each Development Milestone [***], then [***]; and

(b) solely with respect to the Development Milestone [***], if, on the date such Development Milestone is achieved, [***], then:

(i)if, as of the day immediately preceding the date such Development Milestone is achieved, [***], then [***]; or

(ii)if, as of the day immediately preceding the date such Development Milestone is achieved, [***], then [***]; or

(iii)if, as of the day immediately preceding the date such Development Milestone is achieved, [***], then [***].

For clarity, [***].

*the [***] to achieve this Development Milestone shall [***], but [***]"

(c) In the event of [***], Gritstone shall provide written notice to Genevant [***] within [***] of its occurrence and [***] shall apply in each case [***]:

(i)if [***], then [***];

(ii)if [***];

(iii)upon [***], if [***], then [***]:

(A) [***];

(B) [***];

(C) [***]; or

(D) [***];

(iv)upon [***], if [***], then [***]:

(A) if [***];

(B) if [***];

(C) if [***]; or

(D) if [***];

(v)upon [***], then [***] :

(A) if [***];

(B) if [***];

(C) if [***]; or

(D) if [***];

(vi)Upon [***], if [***], then [***]:

(A) if [***];

(B) if [***]; or

(C) if [***].

4.4 Commercial Milestone Payments.

(a) Subject to the terms and conditions of this Agreement, Gritstone shall pay to Genevant for each Product each of the nonrefundable and noncreditable payments set forth in the table below (each, a "Commercial Milestone Payment") upon the first achievement of the corresponding sales milestone for such Product (each, a "Commercial Milestone") by [***]; provided that, if, [***], then: [***]; and [***].

Commercial Milestone	Commercial Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]

[***]	[***]

(b) For each Product, each Commercial Milestone Payment shall be due to Genevant [***]. For the avoidance of doubt, for each Product: [***].

4.5Royalty Payments. Gritstone shall pay to Genevant the royalty on Net Sales set forth below on a Product-by-Product and country-by-country basis during the Royalty Payment Term for such Product in such country (the "Royalty"):

[***]

provided that, notwithstanding the foregoing, with respect to any Product:

(a) if [***], then [***]; and
(b) in the event that, [***]:

(i)if [***]; and

(ii)from and after [***].

Following expiry of the Royalty Payment Term in respect of any Product or country (x) the licenses granted by Genevant to Gritstone with respect to such Product and country become fully paid-up, sublicensable (subject to Section 2.2), royalty-free, exclusive, transferable, perpetual and irrevocable licenses, and (y) the obligation of Gritstone to pay any Royalty or Commercial Milestones with respect to sales of such Product in such country shall terminate.

4.6 Royalty Reductions.

(a) (i) The Royalty due and payable under Section 4.5 for [***] with respect to a Product shall be reduced, on a country-by-country basis, by an amount equal to [***]; and (ii) if during the Royalty Payment Term for a Product and country, the manufacture, use and sale of such Product becomes no longer Covered by at least one Valid Claim in such country, the Royalty due and payable [***] shall thereafter be reduced [***]; provided that, notwithstanding clauses (i) and (ii) above, in no event will the Royalty payable by Gritstone to Genevant [***]. For clarity, [***].

(b) Upon [***].

4.7 Royalty Reports; Expense Reports; Records and Audits.

(a) Within [***] during which [***], Gritstone shall provide to Genevant a written report on a Product-by-Product and country-by-country basis (in electronic form) that includes, for [***], (i) [***] of all Products, and (ii) the calculated amount of the Royalty owed by Gritstone to Genevant in respect of the sale of such Products.

(b) Until [***] of the date any book or record is created or such longer period

required by Applicable Laws (the "Record Retention Period"), Gritstone shall maintain and retain complete and accurate books of account and records covering all transactions relating to payment of amounts that may be due under this Article IV. Upon the reasonable advance notice of Genevant [***], Gritstone shall make such books and records available for inspection and audit by Genevant's authorized representative (which shall be a national certified public accounting firm designated by Genevant and reasonably acceptable to Gritstone), subject to reasonable precautions to protect the Confidential Information of Gritstone. Such examinations may not be conducted more than [***] and going back only during the Record Retention Period after receipt of the respective invoice and report. All audits must be conducted during normal business hours of Gritstone and conducted in a manner so as to minimize the impact on the normal operations of Gritstone. The accounting firm conducting any such audit must provide a report of its findings of any such audit to both Parties, may only identify in such report whether the amount of Royalty paid was correct and the actual amount of Royalty payable and may not disclose any other Confidential Information of Gritstone. The auditor's report and all other information disclosed to the auditor or generated by the auditor in such audit shall be the Confidential Information of Gritstone. Genevant shall pay the cost of such audits unless it discovers that Gritstone has underreported aggregate Royalty during the applicable examination period by an amount equal to or greater than [***], in which case the costs of such audit shall be borne by Gritstone. If an audit reveals an underpayment or overpayment, the Party responsible for making payment shall promptly pay to the other Party the amount of the underpayment or overpayment discovered unpaid under this Section 4.7(b), subject to Section 4.10(d).

4.8 Sublicense Revenue. Unless and to the extent otherwise provided in Sections 4.3(b)(i), 4.3(b)(ii), 4.3(c), 4.4(a)(ii), or 4.5, upon [***] Gritstone shall [***]make a nonrefundable and noncreditable payment to Genevant [***], subject to Sections 4.10(a), 4.10(d) and 4.11.

4.9 Contingent Consideration Adjustment. If [***], then [***]; and [***].

4.10 Payment Procedure.

(a) Remittance of payments to Genevant under this Agreement shall be made by means of wire transfer of immediately available funds to a bank account designated in advance in writing by Genevant. All amounts payable to Genevant under this Agreement shall be paid in United States dollars. With respect to Net Sales in a currency other than U.S. dollars, the Net Sales shall be converted to U.S. dollars using Gritstone's then current internal foreign currency translation methodology actually used on a consistent basis in preparing its audited financial statements.

(b) Any Development Milestone Payment owed pursuant to Section 4.3 shall be paid by Gritstone to Genevant as provided in Section 4.3. Any Commercial Milestone Payment owed pursuant to Section 4.4 shall be paid by Gritstone to Genevant within [***] in which the Commercial Milestone triggering the payment of such Commercial Milestone Payment occurred.

(c) Any Royalty shall accrue in accordance with Section 4.5 during the applicable Royalty Payment Term. Royalty obligations that accrue during a [***] shall be paid within [***].

(d) Any payments due from one Party to the other Party under this Article IV that

are not paid within [***] after the date such payments are due (and not being disputed in good faith) shall bear interest from the date such unpaid payments are due until paid in full at the lesser of: (i) [***] per year above the prime rate quoted by the Wall Street Journal (U.S., Eastern Edition) in effect on the date that such payment would have been first due, and (ii) the highest amount of interest permitted by Applicable Laws. The foregoing interest shall be in addition to any other remedies that either Party may have pursuant to this Agreement.

4.11Taxes. Gritstone may deduct or withhold from any payments due to Genevant amounts for payment of any withholding taxes that are required by law to be paid to any Governmental Authority with respect to such payments. Gritstone will give proper evidence from time to time as to the payment of any such tax. Gritstone is responsible for paying any local, state or federal taxes, levies or duties assessable by tax authorities in the applicable jurisdiction, excluding only taxes based on Genevant's net income. Genevant will provide Gritstone all necessary documents and correspondence, and will also use reasonable efforts to provide to Gritstone any other cooperation or assistance on a reasonable basis as may be necessary, to enable Gritstone to claim exemption from such deduction or withholding taxes. The Parties will cooperate with each other in seeking relief or reduction in the deduction or withholding of any tax under any double taxation or other similar treaty or agreement from time to time in force and in seeking to receive a refund of any withholding tax or to claim a foreign tax credit.

ARTICLE V - ADDITIONAL OBLIGATIONS

5.1 Obligations of Gritstone; Covenants.

(a) As between the Parties, Gritstone shall be solely responsible, at its sole expense and discretion, for identifying and selecting Payloads and Developing Products.

(b) Gritstone shall use Commercially Reasonable Efforts to Develop, obtain Marketing Authorization Approval for, and, following receipt of Marketing Authorization Approval, Commercialize [***] for the Field in each Major Market, in each case including through its Affiliates and Sublicensees. For purposes of this Section 5.1, Commercially Reasonable Efforts shall be determined on a Major Market-by-Major Market basis, and it is anticipated that the level of effort may be different for different Major Markets and may change over time, reflecting changes in the status of the respective Major Markets; provided that failure by Gritstone (itself or through any of its Affiliates or Sublicensees) to undertake any material Research, Development, Manufacturing, or Commercialization activity, including planning activity, in respect of at least one Product for a period of [***] shall, for clarity but without limitation, constitute a breach of this Section 5.1(b).

(c) If and to the extent required (i) by Applicable Laws in the Territory or (ii) to meet notice requirements applicable in the Territory to enforce a patent and recover damages for infringement, Gritstone shall mark, and contract with its sublicensees to mark, each Product for which Marketing Authorization Approval (or EUA) is obtained for the Field anywhere in the Territory with the number of each patent included in the Licensed Intellectual Property that cover such Product.

5.2Obligations of Genevant. At the request, and subject to the approval, of Gritstone, Genevant shall prepare CMC sections of IND, IMPD (Investigational Medicinal Product Dossier),

Marketing Authorization Approval submissions for the Product and provide reasonable subject matter expert support to respond to questions from Regulatory Authorities, and provide reasonable assistance necessary for release of Product for use in clinical trials anywhere in the Territory. Without limiting the foregoing, Genevant shall provide to Gritstone, upon reasonable request and to the extent in Genevant's possession, relevant CMC information, nonclinical and clinical data, and nonclinical and clinical documentation in support of Marketing Authorization Approvals and applications therefor or to support responses to requests from or inquiries of Regulatory Authorities, including INDs, biologics license applications and other regulatory filings, investigational brochures, and research reports related thereto. Gritstone will compensate Genevant for such activities at the FTE Rate.

5.3Ownership of Approvals, INDs and Registration Filings. As between the Parties, Gritstone shall be solely responsible for, and shall have the decision-making authority in respect of, preparing, determining final content, prosecuting and maintaining in its name INDs and any Marketing Authorization Approvals for Products in the Field. Gritstone shall own, in their entirety,
(a) all Product-specific nonclinical and clinical data and reports, including those arising from clinical trials conducted for any Product, and (b) all Marketing Authorization Approvals and applications therefor, including INDs, biologics license applications and other regulatory filings, related thereto.

5.4Regulatory Authority Communications. As between the Parties, Gritstone shall be solely responsible for initiating and responding to any communications related to any Product from any Regulatory Authority, including meetings with any Regulatory Authorities, at its sole cost and expense. Genevant shall use Commercially Reasonable Efforts to provide assistance reasonably requested by Gritstone in connection with the foregoing activities, subject to compensation from Gritstone at the FTE Rate.

5.5Compliance with Law. Both Genevant and Gritstone, and their respective Affiliates, shall perform their respective obligations under this Agreement in compliance with Applicable Laws. The Parties shall cooperate with each other to provide reasonable assistance and take all actions that are necessary to comply with any Applicable Laws in connection with their respective Regulatory Authority obligations in relation to a Product.

5.6Regulatory Authority Inspections. If a Regulatory Authority desires to conduct an inspection or audit of any facility in which any Development or Manufacturing activities are being carried out under this Agreement by or on behalf of Genevant or any data generated in the conduct of activities under this Agreement by or on behalf of Genevant, then (a) the Party receiving notice of such inspection or audit shall promptly notify the other Party of such inspection or audit, and
(b) Genevant shall (i) cooperate in reasonable respects with such Regulatory Authority during such inspection or audit, (ii) reasonably update Gritstone during (in the case of multi-day inspections or audits) and following such inspection or audit of any information relating to Products, (iii) promptly provide to Gritstone the inspection or audit observations of such Regulatory Authority relating to such activities or data; provided that Genevant shall have the right to redact any material from such inspection or audit observations that do not relate to the Products, (iv) prepare the response to any such observations, (v) provide a copy of such planned response to Gritstone to the extent it relates to a Product, shall consult with Gritstone concerning the response of Genevant to each such communication and, if such response affects the Product specifications or any Marketing

Authorization Approval (or Gritstone's obligations to comply with any legal requirements), such response shall be subject to Gritstone's approval, and (vi) conform its activities under this Agreement to any commitments made in such response. To the extent reasonably practicable and not otherwise prohibited by Applicable Laws or any contractual obligation to a Third Party, Genevant shall permit Gritstone the opportunity to be present on site during (but not directly participate in) any such inspection.

ARTICLE VI - INTELLECTUAL PROPERTY

6.1 Ownership.

(a) Subject to the licenses granted by Genevant in Sections 2.1 and 2.5(a), Genevant is and shall at all times remain the sole and exclusive owner, regardless of inventorship, of all:

(i) Genevant Background IP;

(ii) Genevant Outside Foreground IP;

(iii) Genevant's Confidential Information;

(iv)all inventions that: (A) are generated, created, conceived or reduced to practice in the performance of an R&D Support Plan, or the technology transfer set forth in Section 3.4, or any other activities conducted under this Agreement (all of the foregoing, collectively "Agreement Activities") by or on behalf of (x) Genevant or its Affiliates alone, (y) Gritstone alone, or (z) Genevant or its Affiliates jointly with Gritstone; and (B) either (x) constitute an improvement, enhancement or derivative of any Genevant Background IP or, except in the case of clause (A)(y) above, Genevant Outside Foreground IP, or (y) are otherwise directed to LNPs; and (C) does not constitute an improvement, enhancement or derivative of any Gritstone Background IP or Payload IP (clauses (i)-(iv), collectively, "Genevant IP").

(b) Notwithstanding the foregoing, Genevant IP does not and will not include any Payload IP or Product IP or any improvements, enhancements or derivatives of Gritstone Background IP. Gritstone hereby assigns and agrees to assign to Genevant all of its right, title and interest to the Genevant IP and further agrees that it shall, and shall cause its Affiliates to, execute and deliver such additional documents, instruments, conveyances, and assurances and take such further actions as may be reasonably required to ensure that all right, title, and interest in the Genevant IP is effectively transferred to and held by Genevant or its designee.

(c) Subject to the licenses granted by Gritstone under Section 2.5(b), Gritstone is and shall at all times remain the sole and exclusive owner, regardless of inventorship, of:

(i) all Gritstone Background IP and Gritstone Outside Foreground IP;

(ii) Gritstone's Confidential Information, including Payload Material;

(iii)all inventions that (A) are generated, created, conceived or reduced to

practice in the performance of the Agreement Activities by or on behalf of (x) Gritstone alone, (y) Genevant or its Affiliates alone or (z) Gritstone jointly with Genevant or its Affiliates, and (B) constitute an improvement, enhancement or derivative of Gritstone Background IP, Payload IP or, solely in the case of clause (A)(x) above, Gritstone Outside Foreground IP and neither (x) also constitute an improvement, enhancement or derivative of any Genevant Background IP or, except in the case of clause (A)(x) above, Genevant Outside Foreground IP nor (y) are otherwise directed to LNPs; and

(iv) all Product IP and Payload IP (clauses (i)-(iv), collectively, "Gritstone IP").

(d) Genevant hereby assigns and agrees to assign to Gritstone all of its right, title and interest to the Gritstone IP and further agrees that it shall, and shall cause its Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to ensure that all right, title, and interest in the Gritstone IP is effectively transferred to and held by Gritstone.

(e) Except as set forth in Sections 6.1(a) - 6.1(c), which applicable Section shall for clarity control in the event of any conflict with this Section 6.1(e), but in each case subject to the licenses granted by Genevant in Sections 2.1 and 2.5(a):

(i)inventorship of Intellectual Property conceived, reduced to practice or otherwise created in the performance of activities conducted under this Agreement shall be determined by the inventorship laws of the United States;

(ii)all data, results and inventions generated, conceived, reduced to practice or otherwise created solely by or on behalf of Genevant or its Affiliates in the performance of Agreement Activities shall be owned by Genevant (the "Genevant Sole IP");

(iii)all Intellectual Property (other than Payload IP or Product IP) generated, conceived, reduced to practice or otherwise created solely by or on behalf of Gritstone in the performance of Agreement Activities shall be owned by Gritstone (the "Gritstone Sole IP"); provided that Gritstone hereby grants to Genevant a nonexclusive, sublicensable, worldwide right and license under Gritstone's right in any Gritstone Sole IP related or directed to LNPs, including any such Gritstone Sole IP that constitutes an improvement, enhancement or derivative of any Genevant Background IP or Genevant Outside Foreground IP; and

(iv)all Intellectual Property generated, conceived, reduced to practice or otherwise created jointly by employees, consultants, or contractors of Genevant or its Affiliates and by employees or Permitted Contractors of Gritstone in the performance of the Agreement Activities shall be owned jointly by the Parties ("Joint IP").

(f) Each Party shall have an undivided interest in Joint IP, which may be sublicensed to Third Parties, and any ownership rights therein may be transferred, in whole or in part, by each Party (unless otherwise prohibited by this Agreement and subject to any licenses thereunder granted under this Agreement); provided, however, that each Party agrees not to transfer any of its ownership interest in any of the Joint IP without securing the transferee's written

agreement to be bound by the terms of this Section 6.1(f). Neither Party hereto shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint IP outside the scope of this Agreement. The provisions governing Joint IP set forth in this Section 6.1(f) shall survive the expiration or termination of this Agreement. To the extent necessary to effect the intent of this Section 6.1(f), each Party grants to the other Party a nonexclusive, royalty-free, worldwide, sublicensable license under such Party's interest in Joint IP, and all intellectual property rights therein, to make, use, sell, offer for sale and import the relevant Joint IP, for all purposes, subject to the license and rights granted under this Agreement.

(g) Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest or other right, title or interest in or to any other Intellectual Property or Confidential Information of the other Party, whether by implication, estoppel or otherwise, including any items Controlled, delivered, or developed by the other Party.

(h) The Parties agree that this Agreement constitutes a joint research agreement for purposes of 35 U.S.C. §102(c).

6.2 Prosecution and Maintenance of Patents.

(a) Genevant shall have the sole right and responsibility, in its sole discretion and at its sole cost and expense, to file, prosecute, maintain or abandon patent protection in the Territory for Genevant Patents (and any Patent within Genevant IP), including patent term extensions and defending opposition, re-examination, post-grant review and similar proceedings. Genevant shall (i) use reasonable efforts to notify Gritstone of all material developments in connection with prosecuting and maintaining the Genevant Patents that cover any Genevant LNP that, to Genevant's knowledge, is included in any Product and (ii) provide Gritstone with updates with respect to the foregoing upon Gritstone's reasonable request.

(b) Gritstone shall have the sole right and responsibility, in its sole discretion and at its sole cost and expense, to file, prosecute, maintain or abandon patent protection in the Territory for any Patent within Gritstone IP, including patent term extensions and defending opposition, re-examination, post-grant review and similar proceedings.

(c) Subject to Section 6.2(d), [***], by counsel it selects and to whom [***] consents (such consent not to be unreasonably withheld, delayed or conditioned), shall be responsible for the preparation, filing, prosecution and maintenance of the Joint Patents in the countries selected by [***] in consultation with [***]. [***] shall provide [***] with access to all substantive documentation, filings and communications to or from the respective patent offices in the Territory with respect to the Joint Patents at reasonable times and on reasonable notice of at least [***]. [***] shall confer with and keep [***] reasonably informed regarding the status of such activities.

(d) In the event that [***] desires to abandon, withdraw or otherwise discontinue the maintenance or prosecution of any Joint Patent anywhere in the Territory, [***] shall provide reasonable prior written notice to [***] of such intention (which notice shall, in any event, be given

no later than [***] prior to the next deadline for any action that may be taken with respect to such Joint Patent with the applicable patent office) and [***] shall have the right, but not the obligation, to assume, at its expense, responsibility for the prosecution and maintenance thereof. In the event that [***] desires to abandon its interest in any Joint Patent anywhere in the Territory, (i) [***] shall provide written notice to [***] and shall thereupon cease to have any cost-sharing obligation in respect thereof and (ii) such Joint Patent shall thereupon become [***].

(e) Except as provided in Section 6.2(d), all out-of-pocket costs and expenses incurred in the preparation, filing, prosecution and maintenance of any Joint Patent in the Territory shall be shared equally by the Parties.

(f) Notwithstanding anything in this Agreement to the contrary, (i) Genevant shall not file a Patent that includes any claims directed to any Gritstone IP or Gritstone Sole IP and
(ii) Gritstone shall not file a Patent that includes any claims directed to any Genevant IP or Genevant Sole IP, in each case without the other Party's prior written consent.

6.3 Third Party Infringement of Genevant Patents, Joint Patents, and Product Patents.

(a) Each Party shall use reasonable efforts to promptly report in writing to the other Party any known or suspected infringement during the Term of any of the Joint Patents or [***], such Product Patents, in each case by a Third Party making, using or selling a COVID mRNA Vaccine in the Field (each, a "Collaboration Infringement") of which such Party becomes aware, and provide the other Party with all evidence in its possession supporting or relating to such Collaboration Infringement.

(b) Gritstone shall use reasonable efforts to promptly report in writing to Genevant any known or suspected infringement during the Term of any of the Genevant Patents by a Third Party making, using or selling a vaccine or other product for the Field (each, a "Genevant Patent Infringement") of which Gritstone becomes aware and shall provide Genevant with all evidence in its possession supporting or relating to such Genevant Patent Infringement.

(c) Gritstone shall have the first right to initiate an infringement or other appropriate suit ("Infringement Action") with respect to a Collaboration Infringement or to take such other actions as Gritstone, in its sole discretion, deems appropriate with respect to such Collaboration Infringement, all at Gritstone's sole cost and expense, as applicable; provided that, for clarity, Gritstone shall [***].

(d) Genevant shall have the sole right to initiate an Infringement Action with respect to a Genevant Patent Infringement or to take such other actions as Genevant, in its sole discretion, deems appropriate with respect to such Genevant Patent Infringement, all at Genevant's sole cost and expense, as applicable. For clarity, Genevant shall have the sole right to initiate an Infringement Action with respect to any known or suspected infringement during the Term by a Third Party of any of the (i) Joint Patents by a Third Party making, using or selling a product outside of the Field or (ii) Genevant Patents (and any such infringement or Infringement Action shall be outside the scope of this Agreement).

(e) Gritstone shall (i) notify Genevant promptly after initiating any Infringement

Action commenced under Section 6.3(c) with respect to a Collaboration Infringement, (ii) consult closely with Genevant regarding all aspects of such Infringement Action, and (iii) permit Genevant to have an attorney of its own choosing participate in such Infringement Action. If Gritstone elects not to initiate, pursue or maintain any such Infringement Action with respect to a Collaboration Infringement (in the case of Gritstone, including through Sublicensees) for which it has the first right but not the sole right pursuant to Section 6.3(c), Gritstone shall provide Genevant with prompt written notice of its election when made. Thereafter, with the prior consent of Gritstone, which (A) for clarity may be given or withheld in Gritstone's sole discretion and (B) shall, notwithstanding the foregoing not be required in the case of an election by Gritstone not to initiate, pursue or maintain any such Infringement Action in respect of a Joint Patent, Genevant shall have the right, but not the obligation, to initiate, pursue or maintain any Infringement Action that Genevant deems appropriate with respect to such Collaboration Infringement, all at Genevant's sole cost and expense. Thereafter, Genevant shall consult closely with Gritstone regarding all aspects of such Infringement Action and permit Gritstone to have an attorney of its own choosing participate in such Infringement Action.

(f) Neither Party shall enter into any settlement or compromise in connection with an Infringement Action with respect to a Collaboration Infringement that would (i) admit the validity or enforceability, or invalidity or unenforceability, of Patents owned or controlled by the other Party or (ii) require any payments, concessions, or otherwise bind such other Party, in each case (clauses (i) and (ii)) without such other Party's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned.

(g) Upon the request of Genevant, Gritstone shall cooperate with Genevant in any Infringement Action with respect to a Genevant Patent Infringement by joining as a party if necessary or required by Applicable Laws.

(h) The Parties shall share in the proceeds from any Infringement Action commenced under Section 6.3(c) or Section 6.3(e) with respect to a Collaboration Infringement against a Third Party making, using or selling a Product in the Field, including settlements thereof (the "Proceeds"), as follows:

(i)first, for the costs and expenses, including legal fees, that are incurred by either Party as part of, or in preparation for, the Infringement Action (pro rata);

(ii) then, if the Infringement Action is initiated and maintained by: (A) Gritstone, [***]; or (B) Genevant, [***].

(i) For clarity, [***].

6.4Defense of Claims Brought by Third Parties. Each Party shall promptly notify the other Party if it becomes aware of any claim that Gritstone's actual use, sale or practice of any Product in connection with its exercise of its licenses under Section 2.1 or Section 2.5 infringes, misappropriates, or otherwise violates the Intellectual Property rights of any Third Party.

ARTICLE VII - CONFIDENTIAL INFORMATION AND PUBLICITY

7.1Nondisclosure of Confidential Information. Each Party agrees that, for itself and its Affiliates, until [***] the termination or expiration of this Agreement, a Receiving Party shall maintain all Confidential Information of the Disclosing Party in strict confidence and shall not disclose Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below. For the avoidance of doubt, (a) Genevant's Confidential Information includes Genevant Know-How, Genevant Patents, Genevant IP, Genevant Sole IP, and Joint IP solely directed or solely relating to LNPs and (b) Gritstone's Confidential Information includes Gritstone IP and Gritstone Sole IP. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Gritstone disclose any of Genevant's Confidential Information to [***], except to the extent expressly provided in Section 7.4(c).

7.2Exceptions. The obligations in this Article VII shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent documented proof: (a) was known to the Receiving Party or its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;
(b) is subsequently disclosed to the Receiving Party or its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;
(c) is or otherwise becomes generally available to the public or enters the public domain, either before or after it is disclosed to the Receiving Party, and such public availability is not the result, directly or indirectly, of any fault of, or improper taking, use or disclosure by, the Receiving Party or its Affiliates or anyone working in concert or participation with the Receiving Party or its Affiliates; or (d) except for Product IP, has been independently developed by employees or contractors of the Receiving Party or its Affiliates without the aid, application or use of Confidential Information of the Disclosing Party. Notwithstanding the foregoing, (i) specific Confidential Information disclosed by a Disclosing Party shall not be deemed to be within any exceptions set forth in (a), (b), or (c) above merely because it is embraced by more general information to which one or more of those exceptions may apply, (ii) no combination of information shall be deemed to be within any such exceptions unless the combination itself and its principle of operation are within the public domain and (iii) disclosure of Confidential Information to Regulatory Authorities shall not constitute a public disclosure (i.e., it shall remain Confidential Information after such disclosure), unless such information is made available to the public by the Regulatory Authority. Even though Confidential Information may be within one of the exceptions described in the preceding sentence, the Receiving Party shall not disclose to Third Parties that the excepted Confidential Information was received from the Disclosing Party.

7.3Permitted Use; Protection. Confidential Information of a Disclosing Party may be used by the Receiving Party in the performance of its obligations under this Agreement, including disclosures to Permitted Contractors who are bound by enforceable confidentiality agreements with terms consistent with and at least as protective as this Article VII, as otherwise expressly authorized in this Agreement or as expressly authorized by the Disclosing Party in writing. Notwithstanding anything the contrary herein, Confidential Information that is Licensed Intellectual Property may be used and disclosed by Gritstone in connection with the exercise of the rights granted to it under Article II, subject to and in accordance with the provisions of this Agreement. Each Receiving Party shall take steps to maintain the confidentiality of the Disclosing Party's Confidential Information that are consistent with the steps it takes to maintain the confidentiality of its own Confidential Information of a similar value, but in no event less than commercially reasonable steps; provided, however, that nothing in this Agreement shall be deemed

to eliminate, restrict, or otherwise limit Gritstone's license to use such Confidential Information in accordance with the terms and conditions of this Agreement.

7.4Permitted Disclosures. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is: (a) necessary by either Party to comply with Applicable Laws (including any securities Applicable Laws or the rules of a securities exchange in a relevant jurisdiction) and with judicial process, if such disclosure is subject to an order of the court, or with written consent of the Disclosing Party; provided, however, that, where legally permissible, (i) the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make any disclosure sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, including seeking protective orders or injunctive relief, and (ii) consistent with Applicable Laws, the Disclosing Party shall have the right to suggest reasonable changes to the disclosure to protect its interests, and the Receiving Party shall not unreasonably refuse to include such changes in its disclosure; (b) by Gritstone or its Sublicensees, as necessary or reasonably useful in connection with the Development, Manufacture or Commercialization of a Product that uses or employs Licensed Intellectual Property, including labeling requirements and disclosures in connection with obtaining Marketing Authorization Approvals, so long as the Development, Manufacture or Commercialization of such Product has been and is performed in a manner that complies with the terms and conditions of Gritstone's license to such Licensed Intellectual Property and reasonable steps are taken to maintain the confidentiality of such Confidential Information even when disclosed for such purposes; (c) by either Party in connection with discussions with and to current or prospective investors, acquirers, merger partners, or financing sources and their advisors, provided that such parties are bound by enforceable obligations of confidentiality at least substantially as protective as this Article VII; and (d) as provided in Section 7.6.

7.5Press Release. The Parties shall agree on a mutually acceptable press release to announce this Agreement [***]. Thereafter, except as provided in Section 7.7, neither Party shall issue a press release or public announcement relating to the other Party or the collaboration activities undertaken pursuant this Agreement without the prior written approval of the other Party, which approval shall not be unreasonably withheld, delayed or conditioned (it being understood that, without limitation, withholding approval to a press release or public announcement required by Applicable Laws would be unreasonable). Except as otherwise provided herein, each Party agrees not to use the name, trademark, service mark, or design registered to the other Party or its Affiliates in any publicity, promotional, or advertising material, without prior written approval of the other Party.

7.6Securities Filings. If either Party proposes to file with the Securities and Exchange Commission, or the securities regulators of any state or other jurisdiction, a registration statement or any other disclosure document which describes or refers to this Agreement under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other applicable securities law, the Party shall notify the other Party of such intention and shall provide such other Party with a copy of relevant portions of the proposed filing not less than [***] (or such other period as is reasonable under the circumstances) prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to the Agreement, and shall use reasonable efforts to obtain confidential treatment

of any information concerning the Agreement that such other Party requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel is legally required to be disclosed. No such notice shall be required under this Section 7.6 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by the either Party hereunder or otherwise approved in writing by the other Party.

7.7Terms of this Agreement. Except as otherwise specifically set forth in this Article VII, without the prior consent of the other Party, neither Party shall disclose any terms or conditions of this Agreement (including any schedule or exhibit hereto) to any Third Party nor make any statement to the public regarding the execution or any other aspect of the subject matter of this Agreement (including the Development or Commercialization status of Products), except: (a) to the extent such disclosure is required by Applicable Laws or stock exchange rules or regulations and, to the extent practicable, the other Party is provided with the opportunity sufficiently in advance of disclosure to review such information and seek confidential treatment thereof; (b) for discussions and other disclosures with and to current or prospective investors, lenders, (in the case of Gritstone) Sublicensees, acquirers, merger partners, or financing sources and their advisors; (c) either Party may use the text of a statement previously approved for public dissemination by the other Party; and (d) Genevant shall have the right, in its sole discretion, to issue a press release or otherwise disclose publicly the receipt of any milestone or other payment hereunder. With respect to any disclosures made pursuant to clause (b) above, each such Third Party recipient of Confidential Information shall be subject to obligations of confidentiality and nonuse with respect to such Confidential Information substantially similar to the obligations of confidentiality and nonuse of the Receiving Party pursuant to this Article VII.

ARTICLE VIII - INDEMNIFICATION

8.1Genevant Indemnification. Genevant shall indemnify and defend Gritstone and its Affiliates, and their respective agents, directors, officers, employees, representatives, successors and permitted assigns (the "Gritstone Indemnitees") against and shall hold each of them harmless from any and all losses, costs, damages, fees or expenses ("Losses") actually incurred or suffered by a Gritstone Indemnitee to the extent arising out of or in connection with any claim, suit, demand, investigation or proceeding brought by a Third Party based on: (a) any breach of any representation, warranty or covenant by Genevant under this Agreement; or (b) Genevant's or its Affiliates' gross negligence, willful misconduct or violation of Applicable Laws. The foregoing indemnification shall not apply to the extent that any Losses are due to Gritstone's or any of its Affiliates' or its Sublicensees' gross negligence or willful misconduct or violation of Applicable Laws or are subject to Gritstone's indemnification obligations pursuant to Section 8.2.

8.2Gritstone Indemnification. Gritstone shall indemnify and defend Genevant and its Affiliates, and their respective agents, directors, officers, employees, representatives, successors and permitted assigns (the "Genevant Indemnitees") against and shall hold each of them harmless from any and all Losses actually incurred or suffered by a Genevant Indemnitee to the extent arising out of or in connection with any claim, suit, demand, investigation or proceeding brought by a Third Party based on: (a) any breach of any representation, warranty or covenant by Gritstone under this Agreement; (b) Gritstone's or any of its Affiliates' or Sublicensees' gross negligence, willful misconduct or violation of Applicable Laws; or (c) except as otherwise provided in a supply

agreement, if any, between the Parties or their respective Affiliates, product recall, products' liability or similar claims based on the Development, Manufacture or Commercialization of a Product by Gritstone, its Affiliates or Sublicensees. The foregoing indemnification obligations shall not apply to the extent that any Losses are due to Genevant's or its Affiliates' gross negligence or willful misconduct or violation of Applicable Laws or are subject to Genevant's indemnification obligations pursuant to Section 8.1.

8.3 Tender of Defense; Counsel. Any Person seeking indemnification under this Article VIII (the "Indemnified Party") agrees to give prompt notice in writing to the other Party (the "Indemnifying Party") of the assertion of any claim or the commencement of any action by any Third Party (a "Third-Party Claim") in respect of which indemnity may be sought under this Article VIII. Such notice shall set forth in reasonable detail such Third-Party Claim and the basis for indemnification (taking into account the information then available to the Indemnified Party). The failure to so notify (or to so notify promptly) the Indemnifying Party shall not relieve the Indemnifying Party of its indemnification and hold harmless obligations hereunder, except to the extent such failure shall have materially and adversely prejudiced the Indemnifying Party. The Indemnifying Party shall be entitled to control and appoint lead counsel reasonably satisfactory to the Indemnified Party for such defense by written notice to the Indemnified Party within [***] after the Indemnifying Party has received notice of the Third-Party Claim, in each case at its own expense. The Indemnifying Party shall not be entitled to assume or maintain control of the defense of any Third-Party Claim and shall pay the fees and expenses of one counsel retained by the Indemnified Party if: (a) the Third-Party Claim relates to or arises in connection with any criminal proceeding, action, indictment or allegation; (b) the Third-Party Claim seeks an injunction or equitable relief against an Indemnified Party or any of its Affiliates; or (c) the Indemnifying Party, as reasonably and in good faith determined by the Indemnified Party's counsel, has failed or is failing to prosecute or defend vigorously the Third-Party Claim. Each Indemnified Party shall obtain the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, delayed or conditioned, before entering into any settlement of a Third-Party Claim. Notwithstanding the foregoing, the Indemnifying Party shall not be entitled to enter into or approve any settlement of a Third-Party Claim without the consent of the Indemnified Party (which may be withheld in its sole discretion), if the settlement (i) does not unconditionally release all applicable Indemnified Parties and their Affiliates from all Losses with respect to such Third-Party Claim, (ii) imposes injunctive or other equitable relief against the Indemnified Party or any of its Affiliates, (iii) involves any admission of criminal or similar liability, or (iv) involves any monetary damages that may not be fully covered by the Indemnifying Party. In the event that the Indemnifying Party fails to assume the defense of the Third-Party Claim in accordance with this Section 8.3, (1) the Indemnified Party may defend against the Third-Party Claim in any manner it reasonably may deem appropriate, and (2) the Indemnifying Party shall remain responsible for any Losses of the Indemnified Party as a result of such Third-Party Claim. In circumstances where the Indemnifying Party is controlling the defense of a Third-Party Claim in accordance with this Section 8.3, the Indemnified Party shall be entitled to participate in the defense of any Third-Party Claim and to employ separate counsel of its choice for such purpose, in which case the fees and expenses of such separate counsel shall be borne by such Indemnified Party. Notwithstanding anything herein to the contrary, in circumstances where there is a conflict of interest that would make it inappropriate under applicable standards of professional conduct to have common counsel for the Indemnifying Party and the Indemnified Party, the Indemnified Party shall be entitled to employ separate counsel that is reasonably acceptable to the Indemnifying Party, and the

Indemnifying Party shall pay the reasonable fees and expenses of such separate counsel. Each Party shall cooperate, and cause their respective Affiliates to cooperate, in all reasonable respects in the defense or prosecution of any Third-Party Claim and shall furnish or cause to be furnished such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials or appeals, as may be reasonably requested in connection therewith, all at the expense of the Indemnifying Party.

ARTICLE IX - TERM AND TERMINATION

9.1 Term. The term of this Agreement shall begin on the Effective Date and, unless terminated earlier as provided herein, shall continue until the last to expire Royalty Payment Term (the "Term"); provided that, for clarity, the effective date of early termination of this Agreement shall be the last day of the Term. Following expiry of the Royalty Payment Term in respect of any Product or country, Gritstone shall have the paid-up licenses in respect of such Product and country described in Section 4.5.

9.2 Termination of Agreement for Material Breach.

(a) If either Party commits a material breach of any of its obligations under this Agreement, and such breach or default continues without cure for a period of [***] after delivery by the other Party of written notice reasonably detailing such breach or default, then the other Party shall have the right to terminate this Agreement, with immediate effect, by giving written notice to the breaching Party. Notwithstanding the above, if the breach is capable of being cured, but cure of such breach (other than nonpayment) cannot reasonably be effected within such [***] period but is capable of being cured within [***] after delivery of the written notice reasonably detailing such breach or default (the "Extended Cure Period"), the breaching Party shall deliver to the nonbreaching Party a plan reasonably calculated to cure such breach within such [***] period . So long as the breaching Party is diligently carrying out such plan, the nonbreaching Party shall not have the right to terminate this Agreement until, if the breach or default is not yet cured, expiration of the Extended Cure Period. If the breaching Party fails to diligently carry out such plan and cure such breach or default within the Extended Cure Period, then the nonbreaching Party may terminate this Agreement upon written notice to the breaching Party. For purposes of this Section 9.2(a), whether a breach is a material breach must be considered in light of all of the circumstances.

(b) Notwithstanding anything to the contrary in Section 9.2(a), if the allegedly breaching Party disputes in good faith the existence or materiality of such breach or default and provides notice to the other Party of such dispute within the [***] cure period, such other Party will not have the right to terminate this Agreement in accordance with Section 9.2(a) unless and until (i) it has been determined in accordance with Section 10.7 that this Agreement was materially breached by the allegedly breaching Party (as set forth in Section 9.2(a)), and (ii) such Party failed to cure such breach within [***] following the issuance of the arbitral award in accordance with Section 10.7.

9.3 Termination at Will. Gritstone shall have the right to terminate this Agreement in its entirety at any time in its sole discretion for any reason or no reason at all by giving ninety (90) days' advance written notice to Genevant.

9.4 Termination for Safety, Efficacy, or Regulatory Reasons. Notwithstanding Section 9.3, Gritstone may immediately terminate this Agreement in its entirety or on a Product-by-Product or country-by-country basis by providing written notice to Genevant if: (i) prior to regulatory approval to market and sell a Product for the Field in such country, Gritstone or any Sublicensee determines in good faith, using reasonable medical judgment, that there are material concerns regarding the safety of such Product (a "Safety Failure"); (ii) a Product substantially achieves none of the primary efficacy endpoints (including surrogates or pharmacodynamic markers) of any clinical trial involving the Product (an "Efficacy Failure"); or (iii) any Regulatory Authority takes any action, or raises any objection, that prevents Gritstone or any Sublicensee from importing, exporting, purchasing, or selling any Product or LNPs; provided, however, that Gritstone acts in good faith in making such determination and reasonably consults with Genevant prior to terminating this Agreement due to a Safety Failure or Efficacy Failure.

9.5 Reserved.

9.6 Challenges of Genevant Patents. If Gritstone or any of its Affiliates or Sublicensees directly or indirectly and voluntarily commences or participates in any Challenge, Genevant shall have the right to give a written "Challenge Notice" to Gritstone (which Challenge Notice must be given, if at all, within [***] after the CEO or highest-ranking legal executive of Genevant Sciences Corporation or Genevant Sciences, Inc. first becomes aware that Gritstone or any of its Affiliates or Sublicensees has directly or indirectly and voluntarily commenced or participated in such Challenge) that the licenses granted by Genevant to Gritstone hereunder to such Genevant Patent(s) shall terminate [***] following Gritstone's receipt of the Challenge Notice, and, unless Gritstone or any of its Affiliates or Sublicensees, as applicable, withdraws or causes to be withdrawn all such Challenge(s) within such [***] period, such licenses to such Genevant Patent shall so terminate; provided that, if such action, proceeding or assertion is made by a Sublicensee, (a) the license shall only terminate with respect to the portion of the Field and Territory applicable to the sublicense granted to such Sublicensee, subject to clause (b), and (b) Genevant may not so terminate the license if Gritstone has terminated all sublicenses granted to such Sublicensee hereunder within [***] after Gritstone has received the Challenge Notice. For the purpose of this Section, "Challenge" means any challenge to the validity or enforceability of a Genevant Patent, including by (i) filing a declaratory judgment action in which the applicable Genevant Patent is alleged to be invalid or unenforceable, (ii) becoming party to an interference with the applicable Genevant Patent pursuant to 35 U.S.C. §135 or (iii) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against the applicable Genevant Patent, or petitioning for any form of administrative or judicial (or arbitration) review of the applicable Genevant Patent, including post-grant review, inter partes review, or opposition proceedings; provided, however, that the term Challenge shall not include arguments, or any other statements or allegations, made by or on behalf of Gritstone, its Affiliate, or its Sublicensee that: (A) distinguish the inventions claimed in Patents owned or controlled (except by virtue of this Agreement) by Gritstone, its Affiliate, or its Sublicensee from those claimed in the Genevant Patents (1) in the ordinary course of ex parte prosecution of such patents or patent applications owned or controlled by Gritstone, its Affiliate, or its Sublicensee, including any reissue or reexamination patents or patent applications, or (2) in inter partes, post grant review proceedings, oppositions, nullity proceedings, reissue proceedings, reexamination proceedings, and other similar proceedings before the U.S. Patent & Trademark Office or other agency or tribunal in any jurisdiction, or in any arbitration or litigation, wherein such patents or patent applications owned or controlled by Gritstone, its Affiliate, or its

Sublicensee have been challenged by Genevant or its Affiliates; or (B) are made in connection with a response to a claim or allegation that Gritstone, its Affiliate, or its Sublicensee, or any of their respective direct or indirect customers infringes or may infringe any Patents Controlled or enforceable by Genevant, its Affiliates, or any of their respective successors or assigns. Neither Gritstone's, its Affiliate's, a Sublicensee's, nor any of their employees' participating in or appearing in any such action, proceeding or claim as a result of receiving a subpoena or other court order requiring such participation or appearance shall give rise to a right for Genevant to terminate as set forth in this Section 9.6.

9.7 Rights in Bankruptcy.

(a) Each Party (the "Insolvent Party") shall promptly notify the other Party (the "Solvent Party") in writing upon the initiation of any proceeding in bankruptcy, reorganization, dissolution, liquidation or arrangement for the appointment of a receiver or trustee to take possession of the assets of the Insolvent Party or similar proceeding under law for release of creditors by or against the Insolvent Party or if the Insolvent Party shall make a general assignment for the benefit of its creditors. To the extent permitted by Applicable Laws, if the applicable circumstances described above shall have continued for [***] undismissed, unstayed, unbonded and undischarged, the Solvent Party may terminate this Agreement upon written notice to the Insolvent Party at any time. If Genevant is the Insolvent Party, the rights and remedies granted to Gritstone (as the Solvent Party) pursuant to this Section 9.7(a) shall be in addition to, and not in lieu of, Gritstone's rights and remedies under Section 9.7(b).

(b) Without limiting the foregoing, the Parties acknowledge and agree that all rights and licenses granted under or pursuant to this Agreement to Gritstone, and otherwise will be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code ("U.S. Bankruptcy Code") or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, and, in the event that a case under U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws is commenced by or against Genevant, Gritstone shall have all of the rights set forth in Section 365(n) or comparable provision of applicable bankruptcy or insolvency laws to the maximum extent permitted thereby. Without limiting Gritstone's rights under Section 365(n) or comparable provision of applicable bankruptcy or insolvency laws, if a case under U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws is commenced by or against Genevant, Gritstone will be entitled, to the extent in Genevant's possession, to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in Gritstone's possession, will be promptly delivered to it (a) before this Agreement is rejected by or on behalf of Genevant, within [***] upon Gritstone's written request therefor, unless the Genevant, or its trustee or receiver, elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a), following the rejection of this Agreement by or on behalf of Genevant upon written request therefor by Gritstone. All rights of Gritstone under this Section 9.7(b) are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this Agreement, U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, and any other Applicable Laws. In addition, and notwithstanding anything to the contrary hereunder, to the extent ownership or control of any of Licensed Intellectual Property is transferred or assigned to any Third Party (regardless of the method or

nature of any such transfer or assignment, whether voluntary or involuntary, and whether by merger, operation of law, bankruptcy, or otherwise): (i) such Licensed Intellectual Property shall continue to be licensed hereunder on the terms and conditions set forth herein; (ii) Gritstone shall continue to have the same license rights therein under this Agreement as it had prior to such transfer; and (iii) the licenses to such Licensed Intellectual Property in this Agreement shall be deemed hereby to have been automatically granted by such transferee. To the extent necessary to effectuate clauses (i)-(iii), Genevant hereby agrees to execute any documents and take all other lawful actions reasonably requested by Gritstone.

9.8 Consequences of Expiration or Termination; Survival.

(a) Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing (i.e., where the activity or event giving rise to such obligation has occurred, whether or not any amount in respect thereto is yet due or owing) prior to or upon such expiration or termination, and the provisions of Sections 2.2(c), 4.7(b), 4.10, 4.11, 5.3, 6.1, 6.2 (excluding the last sentence of Section 6.2(a)), 9.7(b), 9.8, 9.9, 10.1(c), and 10.2 through 10.16, Sections 6.3(a), 6.3(c), 6.3(e), 6.3(f) and 6.3(h) (solely with respect to Joint Patents and, in the case of Section 6.3(h), each other Section of this Agreement to the extent necessary to give effect to Section 6.3(h)) and Article I (Definitions), Article VII (Confidential Information and Publicity) (for the term set forth in Section 7.1), and Article VIII (Indemnification) shall survive any expiration or termination of this Agreement.

(b) On the effective date of termination of this Agreement, each Party shall promptly return to the other Party all written Confidential Information of the other Party and all copies thereof (except for one archival copy to be retained solely for the purpose of confirming which information to hold in confidence hereunder and any backup copies generated by such Party's information technology systems).

(c) In the event this Agreement is terminated in accordance with its terms, then the license granted under Section 2.1 shall terminate upon the effective date of such termination, subject to Section 2.2(c). The termination by Genevant of the rights granted to Gritstone under Section 2.1 shall be without prejudice to:

(i) any sublicenses that survive in accordance with Section 2.2(c);

(ii)Genevant's right to receive all payments from Gritstone under this Agreement for which the activity or event giving rise to payment has occurred as of the effective date of termination (whether or not such payment has become due and payable), which for clarity but without limitation shall include Genevant's noncancelable obligations to Third Parties actually and reasonably incurred by Genevant in the performance of an R&D Support Plan or any technology transfer prior to receipt of notice of termination; and

(iii)Genevant's right to receive within [***] after the effective date of such termination, a written report from Gritstone detailing the amount of Product(s) that Gritstone, its Affiliates, Sublicensees and sub-Sublicensees then have completed on hand, the sale of which would, but for the termination, be subject to Royalty.

In addition, with respect to any Product for which Gritstone has obtained a Marketing

Authorization Approval in any country prior to Genevant's receipt of notice of termination, Gritstone shall be allowed to continue to commercialize such Product in such country, whether on its own or through Third Parties, to the extent manufactured prior to the effective date of such termination, for up to [***] from such date, subject to payment to Genevant of the Royalty and any and all other amounts hereunder payable with respect to sales of such Product.

9.9Remedies. The Parties acknowledge and agree that, in the event of a breach or a threatened breach by either Party of this Agreement for which it shall have no adequate remedy at law, the other Party may suffer irreparable damage and, accordingly, may be entitled to injunctive and other equitable remedies to prevent or restrain such breach or threatened breach, in addition to any other remedy they might have at law or at equity. In the event of a breach or threatened breach by a Party of any such provision, the other Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which the other Party may be entitled in law or equity.

ARTICLE X - MISCELLANEOUS

10.1 Representations and Warranties.

(a) Mutual Representations, Warranties, and Covenants. Each Party hereby represents, warrants, and covenants to the other Party that:

(i)as of the Effective Date, it is duly organized and validly existing under the laws of the jurisdiction of its incorporation or formation, and has all necessary power and authority to conduct its business in the manner in which it is currently being conducted, to own and use its assets in the manner in which its assets are currently owned and used, and to enter into and perform its obligations under this Agreement;

(ii)as of the Effective Date, the execution, delivery and performance of this Agreement has been duly authorized by all necessary action on the part of such Party and its Board of Directors or other governing body and no consent, approval, order or authorization of, or registration, declaration or filing with any Third Party or Governmental Authority is necessary for the execution, delivery or performance of this Agreement;

(iii)as of the Effective Date, this Agreement constitutes the legal, valid and binding obligation of such Party, enforceable against it in accordance with its terms, subject to (A) Applicable Laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (B) Applicable Laws governing specific performance, injunctive relief and other equitable remedies;

(iv)such Party shall perform its obligations herein in compliance with all Applicable Laws; and

(v)neither such Party nor any of its Affiliates has ever been, nor to each Party's knowledge has any of its employees have ever been, and neither such Party nor any of its Affiliates shall knowingly use any individual in the performance of Research and Development of Products under this Agreement that has been (A) convicted of a crime for which a Person can be

debarred under Section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 or under 42 U.S.C. Section 1320-7 or (B) sanctioned by, suspended, excluded or otherwise ineligible to participate in any federal health care program, including Medicare and Medicaid or in federal procurement or nonprocurement programs. If at any time this representation and warranty is no longer accurate, Genevant or Gritstone, as the case may be, shall immediately notify the other of such fact.

(b) Genevant Representations, Warranties, and Covenants. Except as provided on Exhibit C attached hereto, Genevant hereby represents, warrants, and covenants to Gritstone as of the Effective Date that:

(i)it is entitled to grant the rights and licenses granted to Gritstone under this Agreement, and it and its Affiliates are not bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it in any way from granting to Gritstone the rights and licenses as set forth in this Agreement;

(ii)[***];

(iii)neither Genevant nor any of its Affiliates has assigned, transferred, conveyed or otherwise encumbered, nor during the Term shall assign, transfer, license, convey or otherwise encumber, its right, title and interest in any Licensed Intellectual Property in a manner that conflicts with or reduces the scope of Gritstone's rights under this Agreement;

(iv)neither Genevant nor any of its Affiliates shall during the Term (A) grant any rights [***] that would prevent it from granting the rights granted to Gritstone under this Agreement [***];

(v)attached hereto as Exhibit D is a complete and accurate list of all published and issued Genevant Patents Controlled by Genevant or any of its Affiliates as of the Effective Date;

(vi)except for Patents or Know-How in-licensed by Genevant under the Existing Third Party Agreements, Genevant solely owns the Licensed Intellectual Property;

(vii)Genevant (A) has not materially breached any provision of the Existing Third Party Agreements, (B) will not take any action that would result in any material breach of any provision of the Existing Third Party Agreements, to the extent, with respect to any Existing Third Party Agreement, such action would provide the licensor thereunder the right to terminate or reduce the scope of rights granted to Genevant under such Existing Third Party Agreement (it being understood that Genevant will be solely responsible for satisfying any financial obligation under the Existing Third Party Agreements), (C) will promptly provide to Gritstone any notice of breach received from the applicable Third Party in connection with the Existing Third Party Agreements and keep Gritstone reasonably apprised of Genevant's progress in curing such breach or resolving the dispute with such Third Party, (D) will not terminate the Existing Third Party Agreements, and (E) will not amend the Existing Third Party Agreements in a way that would prevent it from granting the rights granted to Gritstone under this Agreement, or that would otherwise conflict with or reduce the scope of Gritstone's rights under this Agreement;

(viii)Genevant has not received any written notice of [***] any claims or allegations that (A) a Third Party has any right or interest in or to any Genevant Patent or any other Licensed Intellectual Property or (B) the Genevant Patents are invalid or unenforceable;

(ix)Genevant has not received [***] any claims or allegations that the exploitation of the Licensed Intellectual Property infringes or misappropriates any Intellectual Property rights of any Third Party;

(x)to Genevant's knowledge, the Licensed Intellectual Property does not include any trade secrets that have been misappropriated from any Third Party or obtained in breach of any contractual obligation of Genevant or its employees to a Third Party;

(xi)to Genevant's knowledge, neither Genevant nor any of its Affiliates, nor any of its or their respective officers, employees or contractors, has [***]; and

(xii)to Genevant's knowledge, Genevant has not employed (and, to its knowledge, has not used a contractor or consultant that has employed) any person debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act (or subject to a similar sanction of EMA or foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent), in the conduct of its activities prior to the Effective Date of this Agreement, and no action, suit, claim, investigation or legal or administrative proceeding is pending or, to its knowledge, is threatened, relating to the debarment or conviction of it or, to its knowledge, any such person who has performed services on its behalf prior to the Effective Date.

(c) Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY INTELLECTUAL PROPERTY, PRODUCTS, GOODS, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT OR VALIDITY OF PATENTS WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT PURSUANT TO THIS AGREEMENT SHALL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO ANY SUCH PRODUCT SHALL BE ACHIEVED.

10.2Force Majeure. A Party shall neither be held liable or responsible to any other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement (other than the payment of money) to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, pandemics, acts of God or any acts, omissions or delays in

acting by any Governmental Authority or any other Party, and such affected Party promptly begins performing under this Agreement once such causes have been removed.

10.3Consequential Damages. NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY WITH RESPECT TO THIS AGREEMENT, AND THE ACTIVITIES CONTEMPLATED HEREBY (INCLUDING ANY R&D SUPPORT PLAN), FOR ANY CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL OR SIMILAR DAMAGES, WHETHER FORESEEABLE OR UNFORESEEABLE AND REGARDLESS OF THE CAUSE OF ACTION FROM WHICH THEY ARISE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OCCURRING. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.3 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OF A PARTY OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE VII.

10.4 Assignment; Change of Control.

10.4.1Neither Party shall assign or transfer any of its rights and obligations hereunder without the prior written consent of the other Party, except (a) to a purchaser of all or substantially all of the assets or business of such Party to which this Agreement relates, or to the Successor resulting from any Change of Control, or (b) to an Affiliate; provided, however, that
(i) such assignment to an Affiliate shall not relieve such Party of its obligations herein, and (ii) in each case, the assigning Party shall provide the other Party with written notice of such assignment or transfer within [***] after such assignment or transfer. Any purported transfer or assignment in contravention of this Section 10.4.1 shall, at the option of the nonassigning Party, be null and void and of no effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

10.4.2From and after any Change of Control [***].

10.5 Notices.

Notices to Gritstone shall be addressed to:

[***]

Notices to Genevant shall be addressed to:

[***]

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

[***]

Either Party may change its address by giving notice to the other Party in the manner provided in this Section 10.5. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be (a) sent by certified mail, return receipt requested, postage prepaid, (b) sent via a reputable international express courier service, or (c) sent by electronic transmission, with a copy by regular mail. The effective date of the notice shall be the actual date of receipt by the

receiving party.

10.6Independent Contractors. It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either Party to act as the agent for the other Party.

10.7 Governing Law; Dispute Resolution.

(a) This Agreement shall be governed and interpreted in accordance with the substantive laws of the State of New York, excluding its conflicts of laws principles.

(b) The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the alleged breach thereof. Subject to Section 10.7(h), in the event the Parties cannot resolve such dispute, controversy or claim within a period of [***] from first attempting to do so, then either Party may refer the matter to the Executive Officers of the Parties for resolution by the sending of a notice of dispute(s) for executive resolution (each such notice a "Notice of Dispute(s)"). The Executive Officers of the Parties shall endeavor to meet in person within [***] following transmittal of the Notice of Dispute(s).

(c) Except as expressly set forth in Section 10.7(h), if, after going through this procedure, the Executive Officers are unable to resolve, and a Party wishes to pursue, the matter, such matter, if not an Excluded Claim, shall be finally resolved by binding arbitration administered by JAMS pursuant to JAMS' Streamlined Arbitration Rules and Procedures then in effect (the "JAMS Rules").

(d) The arbitration shall be conducted by a single arbitrator acceptable to both Gritstone and Genevant. If Gritstone and Genevant are unable to agree on an arbitrator, the arbitration shall be conducted by a panel of three (3) neutral arbitrators, each of whom shall have significant legal or business experience in the pharmaceutical industry and none of whom shall be a current or former employee or director, or a current significant shareholder, of either Party, any of their respective Affiliates or any Sublicensee; within [***] after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator within [***] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, the third (3rd) arbitrator shall be appointed by JAMS. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English. Within [***] after selection of the single arbitrator or the third arbitrator, as the case may be, the arbitrator(s) shall conduct the Preliminary Conference (as defined in the JAMS Rules). In addressing any of the subjects within the scope of the Preliminary Conference, the arbitrator(s) shall take into account both the desirability of making discovery efficient and cost-effective and the needs of the Parties for an understanding of any legitimate issue raised in the arbitration. The award rendered by the arbitrator(s) shall be final, binding and nonappealable, and judgment may be entered upon it in any court of competent jurisdiction.

(e) Either Party may apply to the arbitrator(s) for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. The authority of the arbitrator(s) to award punitive or any other type of damages not measured by a Party's compensatory damages shall be subject to the limitation set forth in Section 10.3. Each Party shall

bear its own costs and expenses and attorneys' fees and an equal share of the fees of the arbitrator(s) and any administrative fees of arbitration.

(f) Except to the extent necessary to confirm or enforce an award or as may be required by law, neither Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(g) The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payment made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payment is not due.

(h) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve an Excluded Claim, and no such claim shall be subject to arbitration pursuant to Section 10.7(c).

10.8Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable because it is invalid or in conflict with any law of the relevant jurisdiction, the validity of the remaining provisions shall not be affected and the rights and obligations of the Parties shall be construed and enforced as if the Agreement did not contain the particular provisions held to be unenforceable, provided that the Parties shall negotiate in good faith a modification of this Agreement with a view to revising this Agreement in a manner that reflects, as closely as is reasonably practicable, the commercial terms of this Agreement as originally signed.

10.9No Implied Waivers. The waiver by a Party of a breach or default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of a Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

10.10Headings. The headings of articles and sections contained in this Agreement are intended solely for convenience and ease of reference and do not constitute any part of this Agreement or have any effect on its interpretation or construction.

10.11Entire Agreement; Amendment. This Agreement (along with the attachments) contains the entire understanding of the Parties with respect to the subject matter hereof and thereof and supersede and replace any and all previous or contemporaneous arrangements and understandings, whether oral or written, between the Parties with respect to the subject matter hereof and thereof, excluding the Mutual Nondisclosure Agreement entered into by Genevant and Gritstone on April 19, 2018 and subsequently amended on May 3, 2019, which shall survive with

respect to any Confidential Information disclosed thereunder prior to the Effective Date. This Agreement (including the attachments hereto) may be amended only by a writing signed by each of the Parties. For clarity, the Option and License and Development Agreement between the Parties dated October 20, 2020 shall continue in full force and effect, unaffected by this Agreement.

10.12Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting party shall not apply.

10.13No Third Party Beneficiaries. No Third Party, including any employee of either Party, shall have or acquire any rights by reason of this Agreement.

10.14Further Assurances. Each Party shall provide such further documents or instruments required by the other Party as may be reasonably necessary or desirable to give effect to the purpose of this Agreement and carry out its provisions. Without limiting the foregoing, Gritstone may seek to prepare a notification or application, as applicable, to the Swiss Federal Institute of Intellectual Property (or other relevant patent office in any country of the Territory) describing the rights and licenses granted by Genevant to Gritstone under this Agreement and to file such notification or application (but not a copy of this Agreement itself) to register this Agreement with the Swiss Federal Institute of Intellectual Property (or other relevant patent office in any country of the Territory). In such event, (a) Genevant shall cooperate in reasonable respects with Gritstone in connection with Gritstone's preparation of such notification or application, (b) Gritstone shall file notification or application only in a form mutually agreed with Genevant, and
(c) Gritstone shall promptly provide to Genevant a copy of the filing receipt or other written confirmation of such filing.

10.15Performance by Affiliates. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder, and Affiliates of a Party are expressly granted certain rights herein; provided that each such Affiliate of a Party shall be bound by the obligations of such Party and such Party shall remain liable hereunder for the prompt payment or performance of its obligations hereunder, as applicable.

10.16Counterparts. This Agreement may be executed in any number of counterparts in original or by facsimile or PDF copy, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

[*Signature Page Follows*]

IN WITNESS WHEREOF, authorized representatives of Gritstone and Genevant have executed and delivered this Agreement effective as of the Effective Date.

GRITSTONE ONCOLOGY, INC.

By: /s/ Andrew R. Allen

Name: Andrew R. Allen

Title: President & CEO

GENEVANT SCIENCES GMBH

By:

Name:

Title:

IN WITNESS WHEREOF, authorized representatives of Gritstone and Genevant have executed and delivered this Agreement effective as of the Effective Date.

GRITSTONE ONCOLOGY, INC.

By: Name:
Title:

GENEVANT SCIENCES GMBH

By: /s/ Dr. Markus Rohrwild

Name: Dr. Markus Rohrwild

Title: Managing Director

Exhibit A

[***]

Exhibit B

[***]

Exhibit D Genevant Patents

[***]

Exhibit 10.3

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

AMENDMENT NO. 1 TO NONEXCLUSIVE LICENSE AND DEVELOPMENT AGREEMENT

This **AMENDMENT NO. 1 TO NONEXCLUSIVE LICENSE AND DEVELOPMENT AGREEMENT** (this "***Amendment***"), effective as of the date signed by the last Party to sign below ("***Amendment Effective Date***"), by and between **Gritstone Oncology, Inc.**, having a place of business at 5959 Horton St #300, Emeryville, CA 94608 ("***Gritstone***"), and **Genevant Sciences GmbH**, a limited liability company organized and existing under the laws of Switzerland, having an address of Viaduktstrasse 8, 4051 Basel, Switzerland ("***Genevant***").

BACKGROUND

A. Genevant and Gritstone entered into that certain Nonexclusive License and Development Agreement, dated as of January 15, 2021 (the "***Agreement***").

B. The Parties have mutually agreed to amend the Agreement as follows in accordance with Section 10.11 of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and undertakings contained herein, and on the terms and subject to the conditions set forth herein, the Parties hereby agree as follows:

1. Capitalized terms used and not otherwise defined herein shall have the respective meanings given to such terms in the Agreement.

2. The text of Section 4.6(a) of the Agreement is hereby deleted and replaced in its entirety with the following:

> "(i) The Royalty due and payable under Section 4.5 for [***] with respect to a Product shall be reduced, on a country-by-country basis, by an amount equal to [***]; and (ii) if during the Royalty Payment Term for a Product and country, the manufacture, use and sale of such Product becomes no longer Covered by at least one Valid Claim in such country, the Royalty due and payable [***]; provided that, notwithstanding clauses (i) and (ii) above and notwithstanding Section 4.6(b), in no event will the Royalty payable by Gritstone to Genevant [***]. For clarity, [***]."

3. Except as amended by this Amendment, the Agreement shall continue in full force and effect pursuant to its terms.

4. This Amendment may be executed in two (2) counterparts, each of which shall be deemed an original but all of which together shall constitute one (1) and the same instrument. This Amendment may be executed by each Party by facsimile or electronic (e.g., .pdf) signature and such signature shall be deemed to bind such Party as if it were an original signature.

5. This Amendment shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

[Signature page follows]

IN WITNESS WHEREOF, Genevant and Gritstone have duly executed this Amendment as of the respective dates set forth below, effective as of the Amendment Effective Date.

GRITSTONE ONCOLOGY, INC.	**GENEVANT SCIENCES GMBH**
By: /s/ Andrew Allen	By: /s/ Markus Rohrwild
Name: Andrew Allen	Name: Markus Rohrwild
Title: President and CEO	Title: Managing Director
Date: Jan. 28, 2021	Date: 29-Jan-2021 5:05 AM EST

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Allen, M.D., Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gritstone bio, 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(s) 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 8, 2023

By: /s/ Andrew Allen

Andrew Allen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vassiliki Economides, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gritstone bio, 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(s) 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 8, 2023

By: /s/ Vassiliki Economides

Vassiliki Economides
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Gritstone bio, Inc. (the "Company") for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Andrew Allen, M.D., Ph.D., President and Chief Executive Officer (Principal Executive Officer) of the Company, and Vassiliki Economides, Chief Financial Officer (Principal Financial Officer) of the Company, respectively, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 8, 2023

/s/ Andrew Allen

Andrew Allen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2023

/s/ Vassiliki Economides

Vassiliki Economides
Chief Financial Officer
(Principal Financial Officer)