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

FORM 10-Q

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

For the quarterly period ended September 30, 2020

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 000-23186

BIOCRYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**62-1413174**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4505 Emperor Blvd., Suite 200 **Durham, North Carolina**	**27703**
(Address of principal executive offices)	(Zip Code)

(919) 859-1302
(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	BCRX	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, a 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 ☒

The number of shares of Common Stock, par value $0.01, of the Registrant outstanding as of October 31, 2020 was 176,565,622.

BIOCRYST PHARMACEUTICALS, INC.

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Risk Factor Summary

An investment in BioCryst Pharmaceuticals, Inc. ("we," "us," "our," "BioCryst," or the "Company") involves risks. You should carefully read this entire Quarterly Report on Form 10-Q and consider the uncertainties and risks discussed in the "Risk Factors" section in Part II, Item 1A of this report, which may adversely affect our business, financial condition, or results of operations, along with the other information included in our other filings with the Securities and Exchange Commission, before deciding to invest in the Company. A summary of the principal factors that make an investment in the Company speculative or risky is set forth below.

- The ongoing COVID-19 pandemic could create challenges in all aspects of our business, including, without limitation, delays, stoppages, difficulties, and increased expenses with respect to our and our partners' development, regulatory processes, and supply chains, negatively impact our ability to access the capital or credit markets to finance our operations, or have the effect of heightening many of the risks described below or in the "Risk Factors" section of this Quarterly Report on Form 10-Q.
- We have incurred losses since our inception, expect to continue to incur losses, and may never be profitable.
- We may not be able to continue as a going concern if we do not obtain additional capital.
- Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process, to receive and maintain regulatory approval for the commercial sale of our products, and to successfully commercialize any approved products. The development process and related regulatory processes are complex and uncertain, may be lengthy and expensive, and require, among other things, an indication that our products and product candidates are safe and effective. For example, applicable regulatory agencies could refuse to approve, or impose restrictions or warnings on, our product candidates, require us to conduct additional studies or adopt study designs that differ from our planned development strategies, suspend or terminate our clinical trials, or take other actions that could materially impact the cost, timing, and success of our planned development strategies.
- We rely heavily upon third parties, including development partners, contractors, contract research organizations, and third-party suppliers, manufacturers, and distributors, for many important stages of our product candidate development and in the commercialization of certain of our product candidates. Our failure to maintain these relationships, the failure of any such third party to perform its obligations under agreements with us, or the failure of a such a relationship to meet our expectations could have a material adverse impact on our business, financial condition, and results of operations.
- If we fail to obtain additional financing or acceptable partnership arrangements, we may be unable to complete the development and commercialization of our product candidates or continue operations.
- The commercial viability of any approved product could be compromised if the product is less effective than expected, causes undesirable side effects that were not previously identified, or fails to achieve market acceptance by physicians, patients, third-party payors, health authorities, and others.
- There can be no assurance that our commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain.
- We expect to continue expanding our development and regulatory capabilities and implementing sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties managing our growth, which could disrupt our operations.
- We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced. In addition, developments by others may render our product candidates or technologies obsolete or noncompetitive.
- We are subject to various laws and regulations related to our products and product candidates, and if we or our employees, consultants, or partners do not comply with these laws and regulations, we could face substantial penalties and our reputation could be harmed. In addition, we and our partners may be subject to new legislation, regulatory proposals, and healthcare payor initiatives that may increase our costs of compliance and adversely affect our or our partners' ability to market our products, obtain collaborators, and raise capital.
- If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of those rights would diminish. Legal proceedings to protect or enforce our patents, the patents of our partners, or our other intellectual property rights could be expensive, time consuming, and unsuccessful.
- We face an inherent risk of liability in the event that the use or misuse of our products results in personal injury or death and our product liability insurance coverage may be insufficient.

- We face risks related to our government-funded programs. If the Biomedical Advanced Research and Development Authority or the National Institute of Allergy and Infectious Diseases were to eliminate, reduce, or delay funding from our contracts, this would have a significant negative impact on the programs associated with such funding and could have a significant impact on our revenues and cash flows.
- If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and seek additional remedies.
- Our Second Amended and Restated Senior Credit Facility contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a material adverse effect on our business.
- International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks. For example, our actual or perceived failure to comply with European governmental regulations and other obligations related to privacy, data protection, and information security could harm our business. In addition, the United Kingdom's decision to withdraw from the European Union could result in increased regulatory and legal complexity, which may make it more difficult for us to do business in Europe and impose additional challenges in securing regulatory approval of our product candidates in Europe.
- If our facility incurs damage or power is lost for a significant length of time, our business will suffer.
- A significant disruption in our information technology systems or a cybersecurity breach could adversely affect our business.
- Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.
- Our stock price has been, and is likely to continue to be, highly volatile, which could cause the value of an investment in our common stock to decline significantly.
- Natural disasters, epidemic or pandemic disease outbreaks, trade wars, political unrest, or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators, or third parties with whom we conduct business now or in the future.

- We are subject to legal proceedings, which could result in losses or unexpected expenditure of time and resources.
- If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our product candidates and commercialization of our products and the related expansion of our business will be delayed or stopped.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
September 30, 2020 and December 31, 2019
(In thousands, except per share data)

	2020 (Unaudited)	2019 (Note 1)
Assets		
Cash and cash equivalents	$ 96,492	$ 114,172
Restricted cash	2,213	1,551
Investments	46,827	22,054
Receivables from collaborations	5,422	22,146
Inventories	6,241	-
Prepaid expenses and other current assets	5,241	4,422
Total current assets	162,436	164,345
Investments	3,002	-
Property and equipment, net	7,142	7,347
Other assets	3,646	3,590
Total assets	$ 176,226	$ 175,282
Liabilities and Stockholders' Equity		
Accounts payable	$ 11,616	$ 13,988
Accrued expenses	30,462	21,365
Interest payable	19,304	14,904
Deferred collaboration revenue	432	2,120
Lease financing obligation	925	1,377
Senior credit facility	19,148	9,020
Non-recourse notes payable	29,890	29,561
Total current liabilities	111,777	92,335
Lease financing obligation	3,919	3,406
Senior credit facility	26,893	41,289
Stockholders' equity:		
Preferred stock, $0.001 par value; shares authorized - 5,000; no shares issued and outstanding	-	-
Common stock, $0.01 par value: shares authorized - 450,000; shares issued and outstanding – 176,566 in 2020 and 154,082 in 2019	1,766	1,541
Additional paid-in capital	994,811	877,300
Accumulated other comprehensive income	9	39
Accumulated deficit	(962,949)	(840,628)
Total stockholders' equity	33,637	38,252
Total liabilities and stockholders' equity	$ 176,226	$ 175,282

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
Three and Nine Months Ended September 30, 2020 and 2019
(In thousands, except per share data-Unaudited)

	Three Months		Nine Months	
	2020	2019	2020	2019
Revenues				
Product sales	$ 2,478	$ 335	$ 2,696	$ 2,014
Royalty revenue	254	508	2,243	3,526
Collaborative and other research and development	3,370	932	8,857	3,570
Total revenues	6,102	1,775	13,796	9,110
Expenses				
Cost of product sales	1,517	—	1,517	1,399
Research and development	30,245	25,120	87,610	80,294
Selling, general and administrative	17,195	11,735	46,943	26,632
Royalty	9	18	78	131
Total operating expenses	48,966	36,873	136,148	108,456
Loss from operations	(42,864)	(35,098)	(122,352)	(99,346)
Interest and other income and expense	(312)	402	8,892	1,545
Interest expense	(2,927)	(3,044)	(8,892)	(8,805)
(Loss) gain on foreign currency derivative	(12)	148	31	331
Net loss	$ (46,115)	$ (37,592)	$ (122,321)	$ (106,275)
Unrealized gain (loss) on available for sale investments	6	19	(30)	357
Comprehensive loss	$ (46,109)	$ (37,573)	$ (122,351)	$ (105,918)
Basic and diluted net loss per common share	**$ (0.26)**	**$ (0.34)**	**$ (0.75)**	**$ (0.96)**
Weighted average shares outstanding	**176,521**	**110,416**	**164,127**	**110,308**

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2020 and 2019
(In thousands-Unaudited)

	2020	2019
Operating activities		
Net loss	$ (122,321)	$ (106,275)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	568	539
Stock-based compensation expense	8,907	14,031
Amortization of debt issuance costs	1,061	936
Amortization of premium/discount on investments	106	1
Change in fair value of foreign currency derivative	630	532
Changes in operating assets and liabilities:		
Receivables	16,724	695
Inventory	(6,241)	(127)
Prepaid expenses and other assets	(1,448)	(1,018)
Accounts payable and accrued expenses	6,725	9,975
Interest payable	4,400	1,575
Deferred revenue	(1,688)	—
Net cash used in operating activities	**(92,577)**	**(79,136)**
Investing activities		
Acquisitions of property and equipment	(359)	(263)
Purchases of investments	(49,818)	(3,018)
Sales and maturities of investments	21,907	64,954
Net cash (used in) provided by investing activities	**(28,270)**	**61,673**
Financing activities		
Sale of common stock, net	92,848	—
Sale of pre-funded warrants	14,817	—
Proceeds from senior credit facility	—	19,477
Payment of senior credit facility	(5,000)	—
Net proceeds from common stock issued under stock-based compensation plans	1,164	1,161
Net cash provided by financing activities	**103,829**	**20,638**
(Decrease) increase in cash, cash equivalents and restricted cash	**(17,018)**	**3,175**
Cash, cash equivalents and restricted cash at beginning of period	115,723	28,275
Cash, cash equivalents and restricted cash at end of period	**$ 98,705**	**$ 31,450**

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Three and Nine Months Ended September 30, 2020 and 2019

(In thousands, except per share amounts-Unaudited)

	Common Stock	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2019	**$ 1,541**	**$ 877,300**	**$ 39**	**$ (840,628)**	**$ 38,252**
Net loss	—	—	—	(37,599)	(37,599)
Other comprehensive loss	—	—	(25)	—	(25)
Employee stock purchase plan sales, 110 shares, net	1	265	—	—	266
Stock-based compensation expense	—	2,754	—	—	2,754
Balance at March 31, 2020	**1,542**	**880,319**	**14**	**(878,227)**	**3,648**
Net loss	—	—	—	(38,607)	(38,607)
Other comprehensive loss	—	—	(11)	—	(11)
Exercise of stock options, 193 shares, net	2	530	—	—	532
Issuance of common stock, 22,044 shares, net	220	92,628	—	—	92,848
Issuance of pre-funded warrants, 3,511 warrants	—	14,817	—	—	14,817
Stock-based compensation expense	—	3,280	—	—	3,280
Balance at June 30, 2020	**1,764**	**991,574**	**3**	**(916,834)**	**76,507**
Net loss	—	—	—	(46,115)	(46,115)
Other comprehensive income	—	—	6	—	6
Employee stock purchase plan sales, 137 shares, net	2	364	—	—	366
Stock-based compensation expense	—	2,873	—	—	2,873
Balance at September 30, 2020	**$ 1,766**	**$ 994,811**	**$ 9**	**$ (962,949)**	**$ 33,637**

	Common Stock	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2018	**$ 1,101**	**$ 780,400**	**$ (297)**	**$ (731,969)**	**$ 49,235**
Impact to retained earnings from adoption of ASC 842	—	—	—	238	238
Net loss	—	—	—	(31,054)	(31,054)
Other comprehensive income	—	—	208	—	208
Exercise of stock options, 160 shares, net	2	341	—	—	343
Employee stock purchase plan sales, 47 shares, net	—	220	—	—	220
Stock-based compensation expense	—	3,317	—	—	3,317
Balance at March 31, 2019	**1,103**	**784,278**	**(89)**	**(762,785)**	**22,507**
Net loss	—	—	—	(37,629)	(37,629)
Other comprehensive income	—	—	130	—	130
Exercise of stock options, 100 shares, net	1	413	—	—	414
Stock-based compensation expense	—	5,385	—	—	5,385
Balance at June 30, 2019	**1,104**	**790,076**	**41**	**(800,414)**	**(9,193)**
Net loss	—	—	—	(37,592)	(37,592)
Other comprehensive income	—	—	19	—	19
Employee stock purchase plan sales, 68 shares, net	—	184	—	—	184
Stock-based compensation expense	—	5,329	—	—	5,329
Balance at September 30, 2019	**$ 1,104**	**$ 795,589**	**$ 60**	**$ (838,006)**	**$ (41,253)**

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except per share amounts)
(Unaudited)

Note 1 - Significant Accounting Policies

The Company

BioCryst Pharmaceuticals, Inc. (the "Company") is a biotechnology company that discovers novel, oral, small-molecule medicines. The Company focuses on the treatment of rare diseases in which significant unmet medical needs exist and an enzyme plays the key role in the biological pathway of the disease. The Company was incorporated in Delaware in 1986, and its headquarters is located in Durham, North Carolina. The Company integrates the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design. BioCryst has incurred losses and negative cash flows from operations since inception.

With the funds available at September 30, 2020, the Company believes these resources will be sufficient to fund its planned operations through the second quarter of 2021. The Company has sustained operating losses for the majority of its corporate history and expects that its 2020 expenses will exceed its 2020 revenues. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations. Accordingly, its planned operations raise doubt about its ability to continue as a going concern through 2021. The Company's liquidity needs will be largely determined by the success of operations in regard to the progression of its product candidates in the future. The Company also may consider other plans to fund operations through 2021 including: (1) securing or increasing U.S. Government funding of its programs, including obtaining procurement contracts; (2) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones; (3) raising additional capital through equity or debt financings or from other sources, including royalty or other monetization transactions; (4) obtaining additional product candidate regulatory approvals, which would generate revenue, milestones and cash flow; (5) reducing spending on one or more research and development programs, including by discontinuing development; and/or (6) restructuring operations to change its overhead structure. The Company may issue securities, including common stock, preferred stock, depositary shares, purchase contracts, warrants, debt securities and units, through private placement transactions or registered public offerings in the future. The Company's future liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates, timing, scope and magnitude of its commercial expenses and key development and regulatory events and its decisions in the future.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, including JPR Royalty Sub LLC ("Royalty Sub") and MDCP, LLC ("MDCP"). Both of these subsidiaries were formed to facilitate financing transactions for the Company. Royalty Sub was formed in connection with a $30,000 financing transaction the Company completed on March 9, 2011. See Note 4, Royalty Monetization, for a further description of this transaction. MDCP was formed in connection with a $23,000 senior credit facility that the Company closed on September 23, 2016 and subsequently amended and restated on each of July 20, 2018 and February 5, 2019. See Note 5 for a further description of these transactions. All intercompany transactions and balances have been eliminated.

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the Company's consolidated financial position, results of operations, and cash flows. There were no adjustments other than normal recurring adjustments.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2019 and the notes thereto included in the Company's 2019 Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The balance sheet as of December 31, 2019 has been derived from the audited consolidated financial statements included in the Company's most recent Annual Report on Form 10-K.

Cash and Cash Equivalents

The Company generally considers cash equivalents to be all cash held in commercial checking accounts, certificates of deposit, money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Restricted Cash

Restricted cash as of September 30, 2020 and December 31, 2019 reflects $795 and $134, respectively, in royalty revenue paid by Shionogi & Co., Ltd. ("Shionogi") designated for interest on the PhaRMA Notes (defined in Note 4) and $1,418 and $1,417, respectively, the Company is required to maintain as collateral for a letter of credit associated with the lease execution and build-out of its Birmingham research facilities.

Investments

The Company invests in high credit quality investments in accordance with its investment policy, which is designed to minimize the possibility of loss. The objective of the Company's investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. The Company places its excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of its credit exposure. In accordance with its policy, the Company is able to invest in marketable debt securities that may consist of U.S. Government and government agency securities, money market and mutual fund investments, municipal and corporate notes and bonds, commercial paper and asset or mortgage-backed securities, among others. The Company's investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of three years and requires an average portfolio maturity of no more than 18 months. Some of the securities the Company invests in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe it has a material exposure to interest rate risk arising from its investments. Generally, the Company's investments are not collateralized. The Company has not realized any significant losses from its investments.

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive loss, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in interest and other income in the Consolidated Statements of Comprehensive Loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At September 30, 2020, the Company believes that the cost of its investments is recoverable in all material respects.

The following tables summarize the fair value of the Company's investments by type. The estimated fair values of the Company's fixed income investments are classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP. These valuations are based on observable direct and indirect inputs, primarily quoted prices of similar, but not identical, instruments in active markets or quoted prices for identical or similar instruments in markets that are not active. These fair values are obtained from independent pricing services which utilize Level 2 inputs.

	September 30, 2020				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of U.S. Government and its agencies	$ 45,722	$ 18	$ 6	$ -	$ 45,746
Corporate debt securities	590	4	-	-	594
Certificates of deposit	3,477	9	3	-	3,489
Total investments	$ 49,789	$ 31	$ 9	$ -	$ 49,829

	December 31, 2019				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of U.S. Government and its agencies	$ 10,488	50	$ 23	$ -	$ 10,561
Corporate debt securities	9,742	59	10	(1)	9,810
Certificates of deposit	1,669	7	7	-	1,683
Total investments	$ 21,899	116	$ 40	$ (1)	$ 22,054

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2020 and December 31, 2019.

	September 30, 2020	December 31, 2019
Maturing in one year or less	$ 46,827	$ 22,054
Maturing after one year through two years	3,002	-
Total investments	$ 49,829	$ 22,054

Receivables from Collaborations

Receivables from collaborations are recorded for amounts due to the Company related to reimbursable research and development costs from the U.S. Department of Health and Human Services, royalty receivables from Shionogi, Green Cross Corporation ("Green Cross"), Mundipharma International Holdings Limited ("Mundipharma") and Seqirus UK Limited ("SUL"), and product sales to SUL. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date.

At September 30, 2020 and December 31, 2019, the Company had the following receivables.

	September 30, 2020		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ -	$ 3,547	$ 3,547
Shionogi & Co. Ltd.	1,679	4	1,683
Green Cross Corporation	142	8	150
Mundipharma International Holdings Limited	42	-	42
Total receivables	$ 1,863	$ 3,559	$ 5,422

	December 31, 2019		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 1,353	$ 15,023	$ 16,376
Shionogi & Co. Ltd.	1,336	4	1,340
Green Cross Corporation	2,924	8	2,932
Mundipharma International Holdings Limited	56	-	56
Seqirus UK Limited	1,091	351	1,442
Total receivables	$ 6,760	$ 15,386	$ 22,146

Monthly invoices are submitted to the U.S. Department of Health and Human Services related to reimbursable research and development costs. The Company is also entitled to monthly reimbursement of indirect costs based on rates stipulated in the underlying contract. The Company's calculations of its indirect cost rates are subject to audit by the U.S. Government.

Receivables from Product Sales

Receivables from product sales are recorded for amounts due to the Company related to sales of RAPIVAB. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date.

Inventory

Inventory is stated at the lower of cost and net realizable value, determined under the first-in, first-out ("FIFO") method, or market. The Company expenses costs related to the production of inventories as research and development expenses in the period incurred until such time it is believed that future economic benefit is expected to be recognized, which generally is reliant upon receipt of regulatory approval. Upon regulatory approval, the Company will capitalize costs related to the production of inventories. At September 30, 2020, the Company's inventory consisted of $206 of peramivir raw materials and $6,035 of peramivir work-in-process.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computer equipment is depreciated over a life of three years. Laboratory equipment, office equipment, and software are depreciated over a life of five years. Furniture and fixtures are depreciated over a life of seven years. Leasehold improvements are amortized over their estimated useful lives or the expected lease term, whichever is less.

In accordance with U.S. GAAP, the Company periodically reviews its property and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Property and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Patents and Licenses

The Company seeks patent protection on all internally developed processes and products. All patent related costs are expensed to selling, general and administrative expenses when incurred as recoverability of such expenditures is uncertain.

Accrued Expenses

The Company generally enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when it determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organizations (“CROs”) in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of the Company’s raw materials, drug substance and drug products; and
- professional fees.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company’s behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. As of September 30, 2020 and December 31, 2019, the carrying value of accrued expenses approximates their fair value due to their short-term settlement.

Income Taxes

The liability method is used in the Company’s accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse.

Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss is comprised of unrealized gains and losses on available-for-sale investments and is disclosed as a separate component of stockholders’ equity. Amounts reclassified from accumulated other comprehensive loss are recorded as interest and other income on the Consolidated Statements of Comprehensive Loss. During the nine months ended September 30, 2020, realized gains of $1 were reclassified out of accumulated other comprehensive loss. No reclassifications out of accumulated other comprehensive loss were recorded during the nine months ended September 30, 2019.

Revenue Recognition

Collaborative and Other Research and Development Arrangements and Royalties

The Company recognizes revenue when it satisfies a performance obligation by transferring promised goods or services to a customer. Revenue is measured at the transaction price that is based on the amount of consideration that the Company expects to receive in exchange for transferring the promised goods or services to the customer. The transaction price includes estimates of variable consideration to the extent it is probable that a significant reversal of revenue recognized will not occur.

The Company has collaboration and license agreements with a number of third parties as well as research and development agreements with certain government entities. The Company's primary sources of revenue are license, service, royalty and product sale revenues from these collaborative and other research and development arrangements.

Revenue from license fees, royalty payments, milestone payments, and research and development fees are recognized as revenue when the earnings process is complete and the Company has no further continuing performance obligations or the Company has completed the performance obligations under the terms of the agreement.

Arrangements that involve the delivery of more than one performance obligation are initially evaluated as to whether the intellectual property licenses granted by the Company represent distinct performance obligations. If they are determined to be distinct, the value of the intellectual property licenses would be recognized up-front while the research and development service fees would be recognized as the performance obligations are satisfied. For performance obligations based on services performed, the Company measures progress using an input method based on the effort we expend or costs we incur toward the satisfaction of performance obligation in relation to the total estimated effort or costs. Variable consideration is assessed at each reporting period as to whether it is not subject to significant future reversal and, therefore, should be included in the transaction price at the inception of the contract. If a contract includes a fixed or minimum amount of research and development support, this also would be included in the transaction price. Changes to collaborations, such as the extensions of the research term or increasing the number of targets or technology covered under an existing agreement, are assessed for whether they represent a modification or should be accounted for as a new contract. For contracts with multiple performance obligations, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price using either an adjusted market assessment approach or an expected cost plus margin approach, representing the amount that the Company believes the market is willing to pay for the product or service. Analyzing the arrangement to identify performance obligations requires the use of judgment, and each may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not probable at the inception of the agreement; and (ii) the Company has a right to payment. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss rather than as a reduction in expenses. Under the Company's contracts with the Biomedical Advanced Research and Development Authority within the United States Department of Health and Human Services ("BARDA/HHS") and the National Institute of Allergy and Infectious Diseases ("NIAID/HHS"), revenue is recognized as reimbursable direct and indirect costs are incurred.

Under certain of the Company's license agreements, the Company receives royalty payments based upon its licensees' net sales of covered products. Royalties are recognized at the later of when (i) the subsequent sale or usage occurs, or (ii) the performance obligation to which some or all of the sales-based or usage-based royalty has been satisfied.

Product Sales

The Company's principal sources of product sales are sales of peramivir to our licensing partners and sales of RAPIVAB to the U.S. Department of Health and Human Services under the Company's procurement contract. The Company recognizes revenue for sales when the customer obtains control of the product, which generally occurs upon delivery.

The Company recorded the following revenues for the three and nine months ended September 30, 2020 and 2019:

	Three Months		Nine Months	
	2020	**2019**	**2020**	**2019**
Product sales	$ 2,478	$ 335	$ 2,696	$ 2,014
Royalty revenue	254	508	2,243	3,526
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	3,088	932	7,240	3,570
Torii Pharmaceutical Co., Ltd.	282	—	1,617	—
Total collaborative and other research and development revenues	3,370	932	8,857	3,570
Total revenues	$ 6,102	$ 1,775	$ 13,796	$ 9,110

Contract Balances

The timing of revenue recognition, billings and cash collections results in billed accounts receivable, unbilled receivables (contract assets) and deferred revenue and billings in excess of revenue recognized (contract liabilities) on the Consolidated Balance Sheets.

Contract assets - The Company's long-term contracts, typically the government research and development contracts, are billed as work progresses in accordance with the contract terms and conditions, either at periodic intervals or upon achievement of certain milestones. Often this results in billing occurring subsequent to revenue recognition resulting in contract assets. Contract assets are generally classified as current assets in the Consolidated Balance Sheet.

Contract liabilities - The Company often receives cash payments from customers in advance of the Company's performance resulting in contract liabilities. These contract liabilities are classified as either current or long-term in the Consolidated Balance Sheet based on the timing of when the Company expects to recognize the revenue.

Contract Costs

The Company may incur direct and indirect costs associated with obtaining a contract. Incremental contract costs that the Company expects to recover are capitalized and amortized over the expected term of the contract. Non-incremental contract costs and costs that the Company does expect to recover are expensed as incurred.

Advertising

The Company engages in very limited distribution and direct-response advertising when promoting RAPIVAB. Advertising and promotional costs are expensed as the costs are incurred.

Research and Development Expenses

The Company's research and development costs are charged to expense when incurred. Research and development expenses include all direct and indirect development costs related to the development of the Company's portfolio of product candidates. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of the Company's manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by the Company over the service periods specified in the contracts and estimates are adjusted, if required, based upon the Company's on-going review of the level of services actually performed.

Additionally, the Company has license agreements with third parties, such as Albert Einstein College of Medicine of Yeshiva University ("AECOM"), Industrial Research, Ltd. ("IRL"), and the University of Alabama at Birmingham ("UAB"), which require fees related to sublicense agreements or maintenance fees. The Company expenses sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. The Company expenses maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments, paid to the Company's academic partners upon receipt of consideration from various commercial partners, and other consideration paid to the Company's academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from the Company's commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in the Company's Consolidated Statements of Comprehensive Loss based on their fair values. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock unit awards is based on the grant date closing price of the common stock. Stock-based compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award. In addition, we have outstanding performance-based stock options for which no compensation expense is recognized until "performance" is deemed to have occurred.

Interest Expense and Deferred Financing Costs

Interest expense for the three months ended September 30, 2020 and 2019 was $2,927 and $3,044, respectively, and for the nine months ended September 30, 2020 and 2019 was $8,892 and $8,805, respectively, related to the issuance of the PhaRMA Notes (defined in Note 4) and the Second Amended and Restated Senior Credit Facility (defined in Note 5). Costs directly associated with the issuance of the PhaRMA Notes and the Second Amended and Restated Senior Credit Facility have been capitalized and are netted against the non-recourse notes payable and senior credit facility on the Consolidated Balance Sheets. These costs are being amortized to interest expense over the terms of the PhaRMA Notes and the Second Amended and Restated Senior Credit Facility using the effective interest rate method. Amortization of deferred financing costs and original issue discount included in interest expense was $381 and $341 for the three months ended September 30, 2020 and 2019, respectively, and $1,061 and $936 for the nine months ended September 30, 2020, and 2019, respectively.

Currency Hedge Agreement

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark to market adjustments are recognized in the Company's Consolidated Statements of Comprehensive Loss. Cumulative mark to market adjustments for the nine months ended September 30, 2020 and 2019 resulted in losses of $630 and $532, respectively. Mark to market adjustments are determined by a third-party pricing model that uses quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing Level 2 in the fair value hierarchy as defined by U.S. GAAP. In addition, the Company realized currency exchange gains of $660 and $863 during the first nine months of 2020 and 2019, respectively, associated with the exercise of a U.S. dollar/Japanese yen currency option under the Currency Hedge Agreement. The Company is also required to post collateral in connection with the mark to market adjustments based on thresholds defined in the Currency Hedge Agreement. As of September 30, 2020 and December 31, 2019, no hedge collateral was posted under the agreement.

Net Loss Per Share

Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options, warrants and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive. The calculation of diluted earnings per share for the three months ended September 30, 2020 and 2019 does not include 16,544 and 541, respectively, of such potential common shares, as their impact would be anti-dilutive. The calculation of diluted earnings per share for the nine months ended September 30, 2020 and 2019 does not include 14,154 and 1,892, respectively, of such potential common shares, as their impact would be anti-dilutive.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The most significant estimates in the Company's consolidated financial statements relate to the valuation of stock options, and the valuation allowance for deferred tax assets resulting from net operating losses. These estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Significant Customers and Other Risks

Significant Customers

Other than royalty revenues, the Company's primary sources of revenue that have an underlying cash flow stream are the reimbursement of galidesivir (formerly BCX4430) development expenses earned under cost-plus-fixed-fee contracts with BARDA/HHS and NIAID/HHS and sales of RAPIVAB (peramivir injection) under our procurement contract awarded by the Centers for Disease Control and Prevention. The Company relies on BARDA/HHS and NIAID/HHS to reimburse predominantly all of the development costs for its galidesivir program. Accordingly, reimbursement of these expenses represents a significant portion of the Company's collaborative and other research and development revenues. The completion or termination of the NIAID/HHS and BARDA/HHS galidesivir contracts could negatively impact the Company's future Consolidated Statements of Comprehensive Loss and Cash Flows. The Company recognizes royalty revenue from the net sales of RAPIACTA by Shionogi; however, the underlying cash flow from these royalty payments, except for Japanese government stockpiling sales, goes directly to pay the interest, and then the principal, on the Company's non-recourse notes payable. Payment of the interest and the ultimate repayment of principal of these notes will be entirely funded by future royalty payments derived from net sales of RAPIACTA. Further, the Company's drug development activities are performed by a limited group of third-party vendors. If any of these vendors were unable to perform their services, this could significantly impact the Company's ability to complete its drug development activities.

Risks from Third Party Manufacturing and Distribution Concentration

The Company may rely on single source manufacturers for active pharmaceutical ingredient and finished drug product manufacturing of product candidates in development and on single source distributors for distribution of approved drug products. Delays in the manufacture or distribution of any product could adversely impact the commercial revenue and future procurement stockpiling of the Company's product candidates in development.

Credit Risk

Cash equivalents and investments are financial instruments which potentially subject the Company to concentration of risk to the extent recorded on the Consolidated Balance Sheets. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of approximately 18 months or less. Other than product sale and collaborative partner receivables discussed above, the majority of the Company's receivables from collaborations are due from the U.S. Government, for which there is no assumed credit risk.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. In addition, ASU 2016-13 requires credit losses relating to available-for-sale debt securities to be recorded through an allowance for credit losses. ASU 2016-13 requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates.

The Company adopted ASU 2016-02 as of January 1, 2020. Given the nature of the Company's receivables from collaborators, investment portfolio and other financial assets, adoption of this standard did not have a material effect on the Company's financial position, results of operations or cash flows.

In August 2018, the FASB issued Accounting Standards Update No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40)* ("ASU 2018-15"). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance requires entities to capitalize costs for certain implementation activities in the application development stage and expense the capitalized implementation costs over the expected term of the hosting arrangement. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company elected to adopt this standard early, beginning October 1, 2019 on a prospective basis. Adoption did not have a material effect on the Company's financial position, results of operations or cash flows.

Note 2 - Stock-Based Compensation

As of September 30, 2020, the Company had three stock-based employee compensation plans: the Amended and Restated Stock Incentive Plan ("Incentive Plan"), the Amended and Restated Inducement Equity Incentive Plan ("Inducement Plan") and the Amended and Restated Employee Stock Purchase Plan ("ESPP"). The Incentive Plan was amended and restated on March 19, 2020 and approved by the Company's stockholders on May 12, 2020. The Inducement Plan was adopted by the Board of Directors on April 24, 2019 and amended and restated by the Board of Directors in February 2020 and in July 2020. The ESPP was amended and restated in March 2020 and approved by the Company's stockholders on May 12, 2020. Stock-based compensation expense of $8,907 ($7,492 of expense related to the Incentive Plan, $1,053 of expense related to the Inducement Plan, and $362 of expense related to the ESPP) was recognized during the first nine months of 2020, while $14,031 ($13,635 of expense related to the Incentive Plan, $164 of expense related to the Inducement Plan and $232 of expense related to the ESPP) was recognized during the first nine months of 2019.

There was approximately $21,884 of total unrecognized compensation cost related to non-vested stock option awards granted by the Company as of September 30, 2020. That cost is expected to be recognized as follows: $2,708 during the remainder of 2020, $8,461 in 2021, $6,983 in 2022, $3,137 in 2023 and $595 in 2024. In addition, the Company has outstanding performance-based stock options for which no compensation expense is recognized until "performance" has occurred and the award vests.

Stock Incentive Plan

The Company grants stock option awards and restricted stock unit awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Stock option awards and restricted stock units granted to employees generally vest 25% each year until fully vested after four years. In August 2013, December 2014 and December 2019, the Company issued 1,032, 1,250 and 315 performance-based stock options, respectively. These awards vest upon successful completion of specific development milestones. As of September 30, 2020, 75% of the August 2013 grants have vested. As of September 30, 2020, 85% of the December 2014 grants have vested. As of September 30, 2020, none of the December 2019 grants have vested. During the nine months ended September 30, 2020, the Company recognized $214 of compensation expense related to one milestone within the December 2019 grants for which achievement became probable. During 2019, the Company recognized $4,998 of stock compensation expense related to two milestones within the December 2014 grants for which achievement became probable. Stock option awards granted to non-employee directors of the Company generally vest over one year. All stock option awards have contractual terms of 10 years. The vesting and exercise provisions of all awards granted under the Incentive Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Incentive Plan.

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2019	968	21,050	$ 5.96
Plan amendment	8,000	-	-
Restricted stock unit awards granted	(31)	-	-
Restricted stock unit awards cancelled	-	-	-
Stock option awards granted	(547)	547	4.86
Stock option awards exercised	-	(193)	2.76
Stock option awards cancelled	3,030	(3,030)	6.90
Balance September 30, 2020	11,420	18,374	$ 5.85

For stock option awards granted under the Incentive Plan during the first nine months of 2020 and 2019, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value per share of the awards granted during the first nine months of 2020 and 2019 was $3.35 and $4.57, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method.

Inducement Equity Incentive Plan

The Company has the ability to grant stock option awards to newly-hired employees as inducements material to each employee entering employment with the Company. Stock option awards granted to newly hired employees are granted with an exercise price equal to the market price of the Company's stock at the date of grant and generally vest 25% each year until fully vested after four years. Each stock option has a term of 10 years and is subject to the terms and conditions of the Inducement Plan. The vesting and exercise provisions of all awards granted under the Inducement Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Inducement Plan.

Related activity under the Inducement Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2019	171	1,329	$ 3.60
Plan amendment	2,900	-	-
Stock option awards granted	(2,338)	2,338	3.33
Stock option awards exercised	-	-	-
Stock option awards cancelled	155	(155)	4.20
Balance September 30, 2020	888	3,512	$ 3.42

For stock option awards granted under the Inducement Plan during the first nine months of 2020 and 2019, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value per share of the awards granted during the first nine months of 2020 and 2019 was $2.41 and $2.72, respectively.

The following table summarizes the key assumptions used by the Company to value the stock option awards granted under the Incentive Plan and the Inducement Plan during the first nine months of 2020 and 2019, respectively. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. The expected volatility represents the historical volatility on the Company's publicly traded common stock. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

Weighted Average Assumptions for Stock Option Awards Granted to Employees and Directors under the Plans

	2020	2019
Expected Life in Years	5.5	5.5
Expected Volatility	83.8%	81.0%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	0.4%	2.0%

Employee Stock Purchase Plan ("ESPP")

The Company has reserved a total of 4,475 shares of common stock to be purchased under the ESPP, of which 2,873 shares remain available for purchase at September 30, 2020. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning or 85% of the ending price during six-month purchase intervals. No more than 3 shares may be purchased by any one employee at the six-month purchase dates, and no employee may purchase stock having a fair market value at the commencement date of $25 or more in any one calendar year. The Company issued 246 shares during the first nine months of 2020 under the ESPP. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option were determined using a Black-Scholes option pricing model.

Note 3 - Collaborative and Other Research and Development Contracts

National Institute of Allergy and Infectious Diseases ("NIAID/HHS"). In September 2013, NIAID/HHS contracted with the Company for the development of galidesivir as a treatment for Marburg virus disease (the "Initial Contract"). NIAID/HHS, part of the National Institutes of Health, made an initial award of $5,000 to the Company. The goals of the Initial Contract, including amendments, are to file IND applications for intravenous ("i.v.") and intramuscular ("i.m.") galidesivir for the treatment of Marburg virus disease and other hemorrhagic fever virus diseases, including Yellow Fever and Ebola virus disease, and to conduct an initial Phase 1 human clinical trial. In April 2020, the Company and NIAID/HHS agreed to add a group of COVID-19 patients to the ongoing clinical trial in Yellow Fever. On April 9, 2020, the Company announced it had opened enrollment into a randomized, double-blind, placebo-controlled clinical trial to assess the safety, clinical impact and antiviral effects of galidesivir in patients with COVID-19. As of September 30, 2020, the total contract amount to advance the program through the completion of the Phase 1 clinical program under the Initial Contract is $45,931 and all options have been exercised under the Initial Contract. In August 2020, NIAID/HHS awarded the Company a new contract, with potential aggregate funding up of to $43,908 if all contract options are exercised, to manufacture and evaluate the safety, efficacy and tolerability of galidesivir. NIAID/HHS made an initial award of $6,326 to the Company under this new contract.

Biomedical Advanced Research and Development Authority ("BARDA/HHS"). On March 31, 2015, the Company announced that BARDA/HHS had awarded the Company a contract for the continued development of galidesivir as a potential treatment for diseases caused by RNA pathogens, including filoviruses. This BARDA/HHS contract includes a base contract of $16,265 to support galidesivir drug manufacturing, as well as $22,855 in additional development options that can be exercised by the government, bringing the potential value of the contract to $39,120. As of September 30, 2020, a total of $20,574 has been awarded under exercised options within this contract.

The contracts with NIAID/HHS and BARDA/HHS are cost-plus-fixed-fee contracts. That is, the Company is entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that are related to the development of galidesivir plus a fixed fee, or profit. BARDA/HHS and NIAID/HHS will make periodic assessments of progress, and the continuation of the contract is based on the Company's performance, the timeliness and quality of deliverables, and other factors. The government has rights under certain contract clauses to terminate these contracts. These contracts are terminable by the government at any time for breach or without cause.

U.S. Department of Health and Human Services ("HHS"). On September 6, 2018, the Company announced that HHS had awarded the Company a $34,660 contract for the procurement of up to 50,000 doses of RAPIVAB (peramivir injection) over a five-year period. HHS's purchase of RAPIVAB will supply the Strategic National Stockpile, the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency. The Company delivered two shipments under this contract in 2019 for a total price of approximately $13,864. On September 3, 2020, the Company announced that HHS had exercised an option under this contract to purchase an additional 10,000 doses of RAPIVAB for $6,932.

Torii Pharmaceutical Co., Ltd. ("Torii"). On November 5, 2019, the Company announced that it had entered into the Torii Agreement, granting Torii the exclusive right to commercialize ORLADEYO™ (berotralstat) for the prevention of hereditary angioedema ("HAE") attacks in Japan.

Under the Torii Agreement, the Company received an upfront, non-refundable payment of $22,000 and may be eligible to receive an additional milestone payment of either $20,000 if the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") grants regulatory approval on or before December 31, 2020, or $15,000 if regulatory approval is granted on or before December 31, 2021. In either case, the regulatory milestone payment is contingent upon receipt of a reimbursement price approval from Japan's National Health Insurance system in excess of the threshold specified in the Torii Agreement.

In addition, the Company will be entitled under the Torii Agreement to receive tiered royalty payments based on the amount of annual net sales of ORLADEYO in Japan during each calendar year. If ORLADEYO maintains its Sakigake designation during the PMDA review, the tiered royalty rate will range from 20% to 40% of net sales; otherwise, the tiered royalty rate will range from 15% to 35% of net sales. Torii's royalty payment obligations are subject to customary reductions in certain circumstances, but may not be reduced by more than 50% of the amount that otherwise would have been payable to the Company in the applicable calendar quarter. Torii's royalty payment obligations commence upon the first commercial sale of ORLADEYO in Japan and expire upon the later of (i) the tenth anniversary of the date of first commercial sale of ORLADEYO in Japan, (ii) the expiration of our patents covering ORLADEYO, and (iii) the expiration of regulatory exclusivity for ORLADEYO in Japan. The Company will be responsible for supplying Torii with its required amounts of ORLADEYO. The activities of the parties pursuant to the Torii Agreement will be overseen by a joint steering committee, to be composed of an equal number of representatives from each party to coordinate the development and commercialization of ORLADEYO in Japan.

Under the Torii Agreement, the Company has granted Torii a right of first negotiation ("ROFN") to commercialize ORLADEYO in Japan for the acute treatment of HAE attacks if the Company develops ORLADEYO for such indication and to commercialize any additional kallikrein inhibitor that the Company may develop in the future for use in HAE in Japan. Under both ROFNs, if the parties do not agree to terms with respect to a definitive amendment to the Torii Agreement or new agreement, as applicable, the terms of the amendment or agreement would be set by a third-party arbitrator.

The Company identified performance obligations related to (i) the license to develop and commercialize ORLADEYO, (ii) regulatory approval support and (iii) reimbursement pricing approval support. These were each determined to be distinct from the other performance obligations. The Company allocated the $22,000 upfront consideration to the identified performance obligations using estimation approaches to determine the standalone selling prices under ASC 606. Specifically, in determining the value related to the license, a valuation approach utilizing risk adjusted discounted cash flow projections was used and an expected cost plus margin approach was utilized for the other performance obligations. The Company recognized $20,101 in revenue in 2019 including $19,344 associated with the license which was transferred to Torii at the execution of the Agreement and $757 related to the year to date services provided in the performance of the two approvals. The remaining $1,899 of the $22,000 upfront payment is expected to be recognized as revenue in 2020 as the services are delivered.

Seqirus UK Limited ("SUL"). On June 16, 2015, the Company and SUL, a limited company organized under the laws of the United Kingdom and a subsidiary of CSL Limited, a company organized under the laws of Australia, entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights to develop, manufacture and commercialize RAPIVAB (peramivir injection) for the treatment of influenza except for the rights to conduct such activities in Israel, Japan, Korea and Taiwan (the permitted geographies together constituting the "Territory").

Under the terms of the SUL Agreement, the Company is responsible for fulfilling all post-marketing approval commitments in connection with the FDA's approval of the NDA. Pursuant to rights to sell ALPIVAB in the EU, the Company was also responsible for regulatory filings and interactions with the European Medicines Agency ("EMA"). In accordance with the SUL Agreement, the Company and SUL formed a joint steering committee, composed of an equal number of representatives from each party, to oversee, review and coordinate the conduct and progress of the commercialization of RAPIVAB in the Territory and any additional development. In October 2017, SUL transferred Canadian registration rights for RAPIVAB to the Company.

Under the terms of the SUL Agreement, the Company has received an upfront payment of $33,740 and has achieved all development milestones under the contract totaling $12,000. The Company is entitled under the SUL Agreement to receive tiered royalties at a percentage rate beginning in the mid-teens contingent upon meeting minimum thresholds of net sales, as well as a low-thirties percentage of the gross profit from government stockpiling purchases made outside the U.S. Specifically, the Company receives tiered royalties at a percentage rate in the mid-teens to low-forties on net sales in the U.S. during a Contract Year (defined as July 1 - June 30) and tiered royalties at a percentage rate in the mid-teens to mid-twenties on net sales in the Territory, other than in the U.S., during a Calendar Year, each subject to certain downward adjustments for circumstances or events impacting the overall market opportunity. SUL's royalty payment obligations commenced on the date of the SUL Agreement. The Company developed peramivir under a license from UAB and will owe sublicense payments to them on any future milestone payments and/or royalties received by the Company from SUL.

The Company and SUL entered arbitration proceedings that involved many items under the SUL Agreement including, but not limited to, the EMA approval milestone, which BioCryst maintains is due under the contract as well as appropriately commercializing peramivir in the Territory. On March 4, 2020, the International Court of Arbitration of the International Chamber of Commerce ("ICC Tribunal") delivered a Partial Arbitration Award (the "Partial Arbitration Award") in the arbitration matter between the Company and SUL with respect to the SUL Agreement.

In the Partial Arbitration Award, the ICC Tribunal found that, during the term, SUL materially breached and abandoned its core duties to the Company under the Diligent Efforts (as defined in the SUL Agreement) requirements of the SUL Agreement as applicable in the U.S. The ICC Tribunal granted a declaratory judgment in favor of the Company terminating the SUL Agreement and restoring all rights to peramivir to the Company. The parties have agreed on a transition process for the product, including a full transition of commercialization of the product in the U.S. to the Company as of August 1, 2020 and a full transition of commercialization of the product in Australia as of November 1, 2020. The ICC Tribunal also awarded the Company its attorneys' fees and expenses incurred in securing the declaratory judgment as well as the costs incurred by the Company in the arbitration. Finally, the ICC Tribunal found that SUL breached the SUL Agreement by failing to pay the milestone payment due to the Company within 30 days of the approval of peramivir for adult use in the European Union and awarded the Company $5,000 (plus interest) for this claim. The ICC Tribunal retained jurisdiction for further proceedings relating to the award of attorneys' fees and for any dispute relating to the return to the Company of all rights to peramivir in the Territory. The Company recorded the settlement gain of $8,893 in other income and legal fees and other expenses of $5,026 in selling, general and administrative expenses for the nine months ended September 30, 2020.

Shionogi & Co., Ltd. ("Shionogi"). In February 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. The Company developed peramivir under a license from UAB and will owe sublicense payments to UAB on any future milestone payments and/or royalties received by the Company from Shionogi. In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan. Shionogi has commercially launched peramivir under the commercial name RAPIACTA in Japan and Taiwan.

In December 2017, the Company, on behalf of Royalty Sub, instituted arbitration proceedings against Shionogi in order to resolve a dispute with Shionogi under the Shionogi Agreement regarding the achievement of sales milestones and escalating royalties. The arbitration proceedings have concluded, with the decision that no sales milestones have been achieved and that the royalties will remain the same. The costs associated with the arbitration proceedings are recoverable from the assets of Royalty Sub in accordance with the terms of the indenture and servicing agreement relating to the PhaRMA Notes.

Green Cross Corporation ("Green Cross"). In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross will be responsible for all development, regulatory, and commercialization costs in Korea. The Company received a one-time license fee of $250. The license also provides that the Company will share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea.

Mundipharma International Holdings Limited ("Mundipharma"). In February 2006, the Company entered into an exclusive, royalty bearing right and license agreement with Mundipharma for the development and commercialization of Mundesine, a Purine Nucleoside Phosphorylase ("PNP") inhibitor, for use in oncology (the "Original Agreement"). Under the terms of the Original Agreement, Mundipharma obtained rights to Mundesine in markets across Europe, Asia, and Australasia in exchange for a $10,000 up-front payment.

On November 11, 2011, the Company entered into the Amended and Restated License and Development Agreement (the "Amended and Restated Agreement") with Mundipharma, amending and restating the Original Agreement. Under the terms of the Amended and Restated Agreement, Mundipharma obtained worldwide rights to Mundesine. Commencing on November 11, 2011, Mundipharma controls the development and commercialization of Mundesine and assumes all future development and commercialization costs. The Amended and Restated Agreement provides for the possibility of future event payments totaling $15,000 for achieving specified regulatory events for certain indications and tiered royalties ranging from mid to high single-digit percentages of net product sales in each country where Mundesine is sold by Mundipharma. These royalties are subject to downward adjustments based on the then-existing patent coverage and/or the availability of generic compounds in each country.

Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. ("AECOM" and "IRL" respectively). In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL, (collectively, the "Licensors"). The lead product candidates from this collaboration are forodesine and ulodesine. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, product candidates that might arise from research on these inhibitors. The Company has the option to expand the agreement to include other inventions in the field made by the investigators or employees of the Licensors. The Company agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from $1,400 to almost $4,000 per indication) for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from $150 to $500, that are creditable against actual royalties and other payments due to the Licensors. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by the Licensors.

In May 2010, the Company amended the license agreement through which the Company obtained worldwide exclusive rights to develop and ultimately distribute any product candidates that might arise from research on a series of PNP inhibitors, including forodesine and ulodesine. Under the terms of the amendment, the Licensors agreed to accept a reduction of one-half in the percentage of future payments received from third-party sub licensees of the licensed PNP inhibitors that must be paid to the Licensors. This reduction does not apply to (i) any milestone payments the Company may receive in the future under its license agreement dated February 1, 2006 with Mundipharma and (ii) royalties received from its sub licensees in connection with the sale of licensed products, for which the original payment rate will remain in effect. The rate of royalty payments to the Licensors based on net sales of any resulting product made by the Company remains unchanged.

On November 17, 2011, the Company further amended its agreements with the Licensors whereby the Licensors agreed to accept a reduction of one-half in the percentage of Net Proceeds (as defined in the license agreement) received by the Company under its Amended and Restated Agreement with Mundipharma that will be paid to AECOM/IRL.

On June 19, 2012, the Company further amended its agreements with AECOM/IRL whereby the parties clarified the definition of the field with respect to PNP inhibition and AECOM/IRL agreed to exclusive worldwide license of galidesivir to BioCryst for any antiviral use.

At its sole option and subject to certain agreed upon conditions, any future non-royalty payments due to be paid by the Company to AECOM/IRL under the license agreement may be made either in cash, in shares of the Company's common stock, or in a combination of cash and shares.

On January 6, 2014, the Carbohydrate Chemistry Research Team from Callaghan Innovation Research Limited, formerly Industrial Research Limited, transferred to Victoria University of Wellington ("VUW") to establish the Ferrier Research Institute. The intellectual property rights relating to this research team, and the contracts relating to that intellectual property were transferred to a wholly owned subsidiary of VUW, including the contracts to which BioCryst is a party. The parties executed novation agreements in order to effectuate the transfer. Except for a substitution of parties, the terms and conditions of the contracts are substantially the same.

The University of Alabama at Birmingham ("UAB"). The Company currently has agreements with UAB for influenza neuraminidase and complement inhibitors. Under the terms of these agreements, UAB performed specific research for the Company in return for research payments and license fees. UAB has granted the Company certain rights to any discoveries in these areas resulting from research developed by UAB or jointly developed by UAB with the Company. The Company has agreed to pay single digit royalties on sales of any resulting product and to share in future payments received from other third-party partners. The Company has completed the research under the UAB agreements. These two agreements each have an initial 25-year term, are automatically renewable for five-year terms throughout the life of the last patent and are terminable by the Company upon three months' notice and by UAB under certain circumstances. Upon termination both parties shall cease using the other parties' proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on these agreements, but when the Company licenses this technology, such as in the case of the Shionogi and Green Cross, or commercializes products related to these programs, the Company will owe sublicense fees or royalties on amounts it receives.

Note 4 - Royalty Monetization

Overview

On March 9, 2011, the Company completed a $30,000 financing transaction to monetize certain future royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from the Company the rights to market RAPIACTA in Japan and Taiwan. The Company received net proceeds of $22,691 from the transaction after transaction costs of $4,309 and the establishment of a $3,000 interest reserve account by Royalty Sub, available to help cover interest shortfalls in the future. All of the interest reserve account has been fully utilized with the September 2012 interest payment.

As part of the transaction, the Company entered into a purchase and sale agreement dated as of March 9, 2011 with Royalty Sub, whereby the Company transferred to Royalty Sub, among other things, (i) its rights to receive certain royalty and milestone payments from Shionogi arising under the Shionogi Agreement, and (ii) the right to receive payments under a Japanese yen/US dollar foreign currency hedge arrangement (as further described below, the "Currency Hedge Agreement") put into place by the Company in connection with the transaction. Royalty payments will be paid by Shionogi in Japanese yen, and milestone payments will be paid in U.S. dollars. The Company's collaboration with Shionogi was not impacted as a result of this transaction.

Non-Recourse Notes Payable

On March 9, 2011, Royalty Sub completed a private placement to institutional investors of $30,000 in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the "PhaRMA Notes"). The PhaRMA Notes were issued by Royalty Sub under an Indenture, dated as of March 9, 2011 (the "Indenture"), by and between Royalty Sub and U.S. Bank National Association, as Trustee. Principal and interest on the PhaRMA Notes are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by the Company to Royalty Sub and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. The PhaRMA Notes bear interest at 14% per annum, payable annually in arrears on September 1st of each year. The PhaRMA Notes have a final legal maturity date of December 1, 2020, at which time the outstanding principal amount of the PhaRMA Notes, together with accrued and unpaid interest, will be due in full. The Company remains entitled to receive any royalties and milestone payments related to sales of peramivir by Shionogi following repayment of the PhaRMA Notes.

Royalty Sub's obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including the Company, except to the extent of the Company's pledge of its equity interests in Royalty Sub in support of the PhaRMA Notes. The Company may, but is not obligated to, make capital contributions to a capital account that may be used to redeem, or on up to one occasion pay any interest shortfall on, the PhaRMA Notes.

In September 2014, Royalty Sub was unable to pay the accrued interest obligation due September 3, 2013. Under the terms of the Indenture, Royalty Sub's inability to pay the full amount of interest payable in September 2013 by the next succeeding Payment Date for the PhaRMA Notes, which was September 1, 2014, constituted an event of default. Accordingly, the PhaRMA Notes and related accrued interest have been classified as current liabilities on the December 31, 2014 balance sheet and thereafter. As a result of the event of default under the PhaRMA Notes, the holders of the PhaRMA Notes may pursue acceleration of the PhaRMA Notes, may foreclose on the collateral securing the PhaRMA Notes and the equity interest in Royalty Sub and exercise other remedies available to them under the Indenture in respect of the PhaRMA Notes. In such event, the Company may not realize the benefit of future royalty payments that might otherwise accrue to it following repayment of the PhaRMA Notes and it might otherwise be adversely affected. Due to the non-recourse nature of the PhaRMA Notes, in the event of any potential acceleration or foreclosure, the primary impact to the Company would be the loss of future royalty payments from Shionogi and legal costs associated with retiring the PhaRMA Notes. In addition, the Company may incur costs associated with liquidating the related Currency Hedge Agreement, which would no longer be required in the event of foreclosure, or if the PhaRMA Notes cease to be outstanding. As the PhaRMA Notes are the obligation of Royalty Sub and non-recourse to the Company, the event of default of the PhaRMA Notes is not expected to have a significant impact on the Company's future results of operations or cash flows. As of September 30, 2020, the PhaRMA Notes remain in default.

The Indenture does not contain any financial covenants. The Indenture includes customary representations and warranties of Royalty Sub, affirmative and negative covenants of Royalty Sub, Events of Default and related remedies, and provisions regarding the duties of the Trustee, indemnification of the Trustee, and other matters typical for indentures used in structured financings of this type.

The PhaRMA Notes are redeemable at the option of Royalty Sub at any time at a redemption price equal to the outstanding principal balance of the PhaRMA Notes being redeemed plus accrued and unpaid interest through the redemption date on the PhaRMA Notes being redeemed.

As of September 30, 2020, the aggregate fair value of the PhaRMA Notes was estimated to be approximately 3% of the PhaRMA Notes carrying value of $30,000. The estimated fair value of the PhaRMA Notes is classified as Level 3 in the fair value hierarchy as defined in U.S. GAAP.

Currency Hedge Agreement

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, the Company has the right to purchase dollars and sell yen at a rate of 100 yen per dollar.

The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark to market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Cumulative mark to market adjustments for the nine months ended September 30, 2020 and 2019 resulted in losses of $630 and $532, respectively.

Note 5 - Senior Credit Facility

On February 5, 2019, the Company entered into a $100,000 Senior Credit Facility with an affiliate of MidCap Financial Services, LLC, as administrative agent (the "Second Amended and Restated Senior Credit Facility"). Borrowings under the Second Amended and Restated Senior Credit Facility will be available in three tranches, with (i) the first tranche comprised of $50,000 funded at closing, which included $30,000 of proceeds that were deemed rolled over from the outstanding principal amount under the Company's prior credit agreement, (ii) the second tranche to be comprised of $30,000, and (iii) the third tranche to be comprised of $20,000, with the second and third tranches to be funded upon the completion of certain contingencies related to the Company's development activities of its product candidates and the establishment of certain financial covenants. On September 10, 2019 the Company executed the first amendment to the Second Amended and Restated Credit Facility which extended the commitment termination date for the second tranche to November 30, 2019. On November 30, 2019, the Company's access to the second tranche expired.

The Second Amended and Restated Senior Credit Facility refinanced and replaced the Amended and Restated Senior Credit Facility dated as of July 20, 2018 (the "Amended and Restated Senior Credit Facility"). The Second Amended and Restated Senior Credit Facility bears a variable interest rate of LIBOR (which shall not be less than 0.5%) plus 8%. The Second Amended and Restated Senior Credit Facility includes an interest-only payment period through June 2020 and scheduled monthly principal and interest payments for the subsequent 30 months. The Company used a portion of the proceeds of the Second Amended and Restated Senior Credit Facility to pay off outstanding amounts under the Amended and Restated Senior Credit Facility, and the remainder will be used for general corporate purposes. Under the Second Amended and Restated Senior Credit Facility, the Company must maintain a minimum cash balance of $25,000 of unrestricted cash at all times.

As of September 30, 2020, the Company had borrowings of $45,000 under the Second Amended and Restated Senior Credit Facility bearing an interest rate of 8.5%. The carrying amount of the debt approximates its fair value based on prevailing interest rates as of the balance sheet date. The remaining scheduled principal repayments of the Second Amended and Restated Senior Credit Facility are as follows:

	Principal Payments
2020	$ 5,000
2021	20,000
2022	20,000
Total	$ 45,000

The debt agreement contains two provisions that if deemed probable would create the recognition of an embedded feature; however, the Company does not believe either provision is probable.

Note 6 - Stockholders' Equity

On April 24, 2020, the Company filed a $500,000 shelf registration statement on Form S-3 with the SEC. This shelf registration statement became effective on May 14, 2020 and allows the Company to sell securities, including common stock, preferred stock, depository shares, purchase contracts, warrants, debt securities and units, from time to time at prices and on terms to be determined at the time of sale. On June 1, 2020, the Company completed an underwritten public offering of 22,044,447 shares of its common stock (including shares issued pursuant to the underwriters' 30-day option to purchase additional shares, which was exercised in full), at a purchase price of $4.50 per share, and pre-funded warrants to purchase 3,511,111 shares of common stock, at a purchase price of $4.49 per pre-funded warrant, for total net proceeds to the Company of $107,665 after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The pre-funded warrants are exercisable, subject to the conditions in the warrant agreement, and have an exercise price of $0.01 per share, which is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, or similar events affecting the Company's common stock and also upon any distributions of assets to the Company's stockholders.

Note 7 – Lease Obligations and Other Contingencies

The Company leases certain assets under operating leases, which primarily consisted of real estate leases, laboratory equipment leases and office equipment leases at September 30, 2020. Certain operating leases provide for renewal options, which can vary by lease. The right-of-use asset and lease liabilities on the Company's Consolidated Balance Sheets represent payments over the lease term, which includes renewal options for certain real estate leases that we are likely to exercise. As part of the Company's assessment of the lease term, the Company elected the hindsight practical expedient, which allows companies to use current knowledge and expectations when determining the likelihood to extend lease options. Renewal options for the Company's leases range from 1 to 5 years in length and begin from 2023 through 2026. At September 30, 2020, the weighted average lease term for the Company's operating leases was 13.7 years. The discount rate used in the calculation of the Company's right-of-use asset and lease liability was determined based on the stated rate within each contract when available, or the Company's collateralized borrowing rate from lending institutions. The weighted average discount rate for the Company's operating leases was 12.8%.

The Company has not made any residual value guarantees related to its operating leases; therefore, the Company has no corresponding liability recorded on its Consolidated Balance Sheets.

Aggregate lease expense under operating leases was $1,321 and $1,064 for the nine-month periods ended September 30, 2020 and September 30, 2019, respectively. Certain operating leases include rent escalation provisions, which the Company recognizes as expense on a straight-line basis. Lease expense for leases with an initial term of twelve months or less was not material.

Future lease payments for assets under operating leases as of September 30, 2020, are as follows:

Remaining Maturities of Lease Liabilities **Year Ending December 31,**	**Operating Leases**
2020	$ 403
2021	851
2022	746
2023	608
2024	577
Thereafter	7,908
Total lease payments	11,093
Less imputed interest	6,249
Total	$ 4,844

Of the Company's total lease liability, $925 is a current liability and $3,919 is a long-term liability at September 30, 2020. The current and long-term portions of the Company's lease liability are presented within "Accrued expenses" and "Other non-current liabilities" on the Consolidated Balance Sheets. The Company's right-of-use asset balance associated with operating leases totaled $3,646 at September 30, 2020. This amount is presented within "Other long-term assets" on the Consolidated Balance Sheets.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains statements of a forward-looking nature relating to future events or the future financial performance of BioCryst. Such statements are only predictions, and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below and elsewhere in this report, as well as those discussed in other filings made by the Company with the Securities and Exchange Commission ("SEC"), including the Company's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See "Information Regarding Forward-Looking Statements."

Cautionary Statement

The discussion herein contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created in Section 21E. Forward-looking statements regarding our financial condition and our results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted within the United States ("U.S. GAAP"), as well as projections for the future. The preparation of these financial statements requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. We are subject to risks common to biotechnology and biopharmaceutical companies, including risks inherent in our drug discovery, drug development and commercialization efforts, clinical trials, uncertainty of regulatory actions and marketing approvals, reliance on collaborative partners, enforcement of patent and proprietary rights, the need for future capital, competition associated with products, potential competition associated with our product candidates and retention of key employees. In order for any of our product candidates to be commercialized, it will be necessary for us, or our collaborative partners, to conduct clinical trials, demonstrate efficacy and safety of the product candidate to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, and obtain market acceptance and adequate reimbursement from government and private insurers. We cannot provide assurance that we will generate significant revenues or achieve and sustain profitability in the future. In addition, we can provide no assurance that we will have sufficient funding to meet our future capital requirements. Furthermore, the ongoing COVID-19 pandemic could create challenges in all aspects of our business, including without limitation delays, stoppages, difficulties and increased expenses with respect to our and our partners' development, regulatory processes and supply chains, could negatively impact our ability to access the capital or credit markets to finance our operations, or could have the effect of heightening many of the risks described in Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

Statements contained in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report which are not historical facts are, or may constitute, forward-looking statements. Forward-looking statements involve known and unknown risks that could cause our actual results to differ materially from expected results. The most significant known risks are discussed in the section entitled "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on any forward-looking statements.

Our revenues are difficult to predict and depend on numerous factors, including the prevalence and severity of influenza in regions for which peramivir has received regulatory approval, seasonality of influenza, our and our collaborative partners' commercialization efforts, resources dedicated to our products by our collaborative partners, regulatory approval decisions for ORLADEYO, ongoing discussions with government agencies regarding future peramivir and/or galidesivir development and stockpiling procurement, as well as entering into, or modifying, licensing agreements for our product candidates. Furthermore, revenues related to our collaborative development activities are dependent upon the progress toward and the achievement of developmental milestones by us or our collaborative partners.

Our operating expenses are also difficult to predict and depend on several factors, including research and development expenses (and whether these expenses are reimbursable under government contracts), drug manufacturing, and clinical research activities, the ongoing requirements of our development programs, and the availability of capital and direction from regulatory agencies, which are difficult to predict. Management may be able to control the timing and level of research and development and selling, general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period-to-period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Overview

We are a biotechnology company that discovers novel, oral, small-molecule medicines. We focus on oral treatments for rare diseases in which significant unmet medical needs exist and an enzyme plays the key role in the biological pathway of the disease. We integrate the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design.

Critical Accounting Policies and Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis, as situations change, and regularly discuss financial events, policies, and issues with members of our audit committee and our independent registered public accounting firm. We routinely evaluate our estimates and policies regarding revenue recognition, administration, inventory and manufacturing, taxes, stock-based compensation, research and development, consulting and other expenses and any associated liabilities.

Recent Corporate Highlights

The outbreak of novel coronavirus ("COVID-19") has severely impacted global economic activity and caused significant volatility in financial markets. To date, our financial condition, results of operations, and liquidity have not been materially impacted by the direct effects of the COVID-19 pandemic. However, as discussed under the caption "Complement-Mediated Diseases" below, the acceleration of COVID-19 has slowed startup of the inadequate responder cohorts in our complement oral Factor D inhibitor program. The COVID-19 pandemic is constantly evolving, and its full impact to our business is uncertain. We are monitoring the COVID-19 pandemic and are making adjustments intended to assist in protecting the safety of our employees and communities while continuing our business activities. We have implemented remote working arrangements where possible and restricted business-related travel. To date, implementation of these measures has not required material expenditures or significantly impacted our ability to operate our business or our internal control over financial reporting and disclosure controls and procedures. We are continuing to monitor developments with respect to the COVID-19 pandemic and its potential impacts on our operations and those of our partners, suppliers, and regulators.

ORLADEYO™ (berotralstat)

ORLADEYO is our lead molecule that is being developed as an oral, once-daily therapy for the prevention of hereditary angioedema ("HAE") attacks. Based on the data from our successful clinical program, including our pivotal Phase 3 clinical trial, APeX-2, and a long-term safety trial, APeX-S, we submitted a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") in December 2019 for approval of oral, once-daily ORLADEYO for the prevention of HAE attacks. In February 2020, the FDA notified us that it had accepted and filed our NDA for review and that our Prescription Drug User Fee Act date for the NDA is December 3, 2020. In the NDA filing acceptance letter, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the NDA.

On February 3, 2020, we announced we had submitted a new drug application to the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") for approval of oral, once-daily ORLADEYO for the prevention of HAE attacks. In Japan, ORLADEYO is being reviewed under the Sakigake designation. The PMDA has confirmed its regulatory review schedule, and we expect an approval decision in December 2020.

On March 30, 2020, we announced that the European Medicines Agency ("EMA") had validated our marketing authorization application ("MAA") submission for approval of ORLADEYO for the prevention of HAE attacks. With this validation, the EMA began its formal review of the MAA under the centralized procedure for all member states of the European Union, Norway, Iceland and Liechtenstein. We expect an opinion from the Committee for Medicinal Products for Human Use within approximately 12 months from MAA validation.

On October 30, 2020, we announced that the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") has granted oral, once-daily ORLADEYO a positive scientific opinion through the Early Access to Medicines Scheme ("EAMS"). Under the EAMS, HAE patients in the U.K. aged 12 years and older can gain access to ORLADEYO for the routine prevention of recurrent attacks of HAE before the drug is granted marketing authorization by the European Commission. We previously announced on June 9, 2020 that we have established an expanded access program in the U.S. through which physicians may be able to request ORLADEYO for HAE patients in the U.S. who do not have access to the program through a clinical trial.

In anticipation of a commercial launch of ORLADEYO, we have completed the build-out of our commercial infrastructure to support the successful launch of ORLADEYO in the U.S. Based on proprietary market research, including analyses of HAE prevalence in the U.S. and market research studies with HAE patients, physicians, and payors in the U.S., we anticipate the commercial market for ORLADEYO has the potential to reach a global peak of more than $500 million in annual sales. These expectations are subject to numerous risks and uncertainties that may cause our actual results, performance or achievements to be materially different. There can be no assurance that regulatory approvals of ORLADEYO will be granted in a timely fashion or at all, that our commercialization methods and strategies will succeed, or that the market for ORLADEYO will develop in line with our current expectations. See the "Risk Factors" section of this Quarterly Report on Form 10-Q, including the information under "Risk Factors—Risks Relating to Our Business—Risks Relating to Drug Development and Commercialization—There can be no assurance that our commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain" for further discussion of these risks.

Complement-Mediated Diseases

Discovered by BioCryst, BCX9930 is a novel, oral, potent and selective small molecule inhibitor of Factor D currently in early clinical development for the treatment of complement-mediated diseases. Based on the safety and proof-of-concept data generated to date in PNH patients, we are working closely with key opinion leaders in hematology and nephrology to map the development strategy across a broad set of indications. Our goal is to develop BCX9930 as a monotherapy for complement-mediated diseases.

On June 27, 2019, we announced that we began enrollment of a Phase 1 trial of BCX9930 for the treatment of complement-mediated diseases. The objectives of the trial are to evaluate the safety and tolerability and characterize the pharmacokinetic ("PK") and pharmacodynamic ("PD") profiles of BCX9930 after single ascending doses ("SAD") and multiple ascending doses ("MAD") in healthy subjects. In part three of the trial, there is an additional objective to demonstrate proof of concept in treatment-naïve paroxysmal nocturnal hemoglobinuria ("PNH") patients and PNH patients who are inadequate responders to C5 therapy by evaluating key biomarkers of effectiveness in PNH patients

taking BCX9930. Based on the safety, tolerability, PK and PD dose-response results from parts 1 and 2 of the Phase 1 trial, we completed additional MAD dosing cohorts in healthy subjects and advanced to part 3 of the trial, a proof of concept ("PoC") study of BCX9930 in treatment-naïve PNH patients and in PNH patients who are inadequate responders to eculizumab or ravulizumab.

On September 30, 2020, we announced new data from treatment-naïve PNH patients receiving doses through 400 mg twice-daily of oral BCX9930 as monotherapy in an ongoing dose-ranging trial. Oral BCX9930 is driving rapid and dose-dependent reductions in key biomarkers, including lactate dehydrogenase ("LDH"), and increasing hemoglobin levels in all PNH patients in the trial. Increases in hemoglobin levels were maintained without transfusions. BCX9930 has been safe and well tolerated at all doses in the trial. No drug-related serious adverse events have been reported.

We are completing the ongoing dose ranging trial in treatment-naïve PNH patients and PNH patients with an inadequate response to C5 inhibitors. Seven treatment-naïve PNH patients are currently receiving BCX9930, with four beyond 12 weeks of therapy, including two with more than 32 weeks on therapy. All seven treatment-naïve patients are continuing to benefit from BCX9930 treatment. Based on the results observed to-date at 400 mg twice-daily and 500 mg twice-daily of oral BCX9930, we plan to add patients at these dose levels, for an overall total of up to 16 subjects with BCX9930 dosed up to 500 mg twice-daily. Because the acceleration of COVID-19 has slowed startup of the inadequate C5 responder cohorts, we expect to report the data from treatment-naïve PNH patients and inadequate C5 responders dosed up to 500 mg twice-daily in the first quarter of 2021.

On August 31, 2020, we announced that the FDA has granted Orphan Drug designation for BCX9930 for the treatment of PNH. Orphan Drug designation qualifies BCX9930 for various development incentives, including tax credits for certain clinical costs, a waiver of the new drug application fee, and a designated period of market exclusivity following approval. Earlier in August 2020, the FDA granted Fast Track designation for BCX9930 in PNH. According to the FDA, the purpose of the Fast Track designation is to get important new drugs to the patient earlier by facilitating the development, and expediting the review, of drugs to treat serious conditions and fill an unmet medical need.

Galidesivir (formerly BCX4430)

Galidesivir, a broad-spectrum antiviral drug, is an adenosine nucleoside analog that acts to block viral RNA polymerase. It is in advanced development for the treatment of COVID-19, Marburg virus disease and Yellow Fever. Phase 1 clinical safety and pharmacokinetics trials of galidesivir by both intravenous and intramuscular routes of administration in healthy subjects have been conducted. In animal studies, galidesivir has demonstrated activity against a variety of serious pathogens, including Ebola, Marburg, Yellow Fever and Zika viruses. Galidesivir has also demonstrated broad-spectrum activity in vitro against more than 20 RNA viruses in nine different families, including coronaviruses, filoviruses, togaviruses, bunyaviruses, arenaviruses, paramyxoviruses, and flaviviruses. BioCryst is developing galidesivir in collaboration with U.S. government agencies and other institutions.

In April 2020, we agreed with the National Institute of Allergy and Infectious Diseases ("NIAID/HHS") to add a group of COVID-19 patients to the ongoing clinical trial in Yellow Fever. On April 9, 2020, we announced that we had opened a randomized, double-blind, placebo-controlled clinical trial to assess the safety, clinical impact and antiviral effects of galidesivir in patients with COVID-19. The trial (NCT03891420) is being funded by NIAID/HHS, part of the National Institutes of Health. In the COVID-19 patients, efficacy measures include qualitative and quantitative changes from baseline, time to clinical improvement, time to hospital discharge, time to undetectable levels (as measured by polymerase chain reaction ("PCR") in respiratory specimens) of SARS-CoV-2, the virus that causes COVID-19, and all-cause mortality. The trial is being conducted in Brazil under a U.S. investigational new drug application, and the protocol also has been approved by the Agência Nacional de Vigilância Sanitária and the Brazilian National Ethics Committee. Part 1 of the clinical trial of galidesivir in COVID-19 patients in Brazil has completed enrollment, and we expect to report results in the fourth quarter. The primary endpoint of part 1 is safety. Data is also being collected on secondary endpoints, including clinical outcomes and virology. Based on recent conversations with NIAID/HHS, the major funding partner for the program, we understand that data from part 1 is a gating item for the program and some evidence of clinical and/or virologic activity is important for the program to advance.

The galidesivir development program is substantially funded with federal funds from NIAID/HHS and by the Biomedical Advanced Research and Development Authority ("BARDA/HHS"). Since September 2013, NIAID/HHS has supported us in developing galidesivir as a therapeutic for Ebola and Marburg viruses. Since March 2015, BARDA/HHS has supported the galidesivir development program for the continued development of galidesivir as a potential treatment for filoviruses.

We have ongoing studies with NIAID/HHS and academic collaborators to assess the activity of galidesivir against SARS-CoV-2, the virus that causes COVID-19, in both in vitro and animal models. We are also working with NIAID/HHS to increase manufacturing yield and expand the current supply of the drug.

On August 31, 2020, we announced that NIAID/HHS awarded us a new $43.9 million contract for the manufacture and evaluation of the safety, efficacy and tolerability of galidesivir and that it also added $2.9 million to its existing contract with us to support the development of galidesivir. The additional funds under these performance-based contracts support the completion of parts 1 and 2 of an ongoing clinical trial of galidesivir in Brazil, conducting a phase 2 clinical trial of galidesivir in non-hospitalized COVID-19 patients at high risk for developing severe disease and complications of COVID-19, conducting a clinical pharmacology trial of galidesivir to determine appropriate dosing in patients with renal impairment, and increasing the supply of galidesivir. These contracts are cost-plus-fixed-fee contracts, and as is customary for government contracts of this nature, the government has the right to terminate these contracts at any time for breach or without cause.

Fibrodysplasia Ossificans Progressiva ("FOP")

The goal of the ALK2 inhibitor project program at BioCryst is to discover and develop orally administered kinase inhibitor drug candidates that are able to slow or prevent the progressive formation of bone in soft tissues, also known as heterotopic ossification ("HO"). Our lead compound, BCX9250, reduced HO in an experimental model of ALK2-driven HO in laboratory rats, with up to 89 percent reduction in volume of HO compared to controls. On November 1, 2019, we announced that we had begun a Phase 1 clinical trial with oral BCX9250 for the treatment of FOP. The Phase 1 trial will evaluate single and multiple ascending doses of oral BCX9250 in healthy volunteers. We expect to report the results from the trial by the end of 2020.

RAPIVAB/ALPIVAB/RAPIACTA/PERAMIFLU (peramivir injection)

On March 4, 2020, the International Court of Arbitration of the International Chamber of Commerce ("ICC Tribunal") delivered a Partial Arbitration Award (the "Partial Arbitration Award") in the arbitration matter between us and SUL with respect to the SUL Agreement for the commercialization of peramivir by SUL. In the Partial Arbitration Award, the ICC Tribunal found that, during the term, SUL materially breached and abandoned its core duties to us under the Diligent Efforts (as defined in the SUL Agreement) requirements of the SUL Agreement as applicable in the U.S. The ICC Tribunal granted a declaratory judgment in favor of us terminating the SUL Agreement and restoring all rights to peramivir to us. We have agreed with SUL on a transition process for the product, including a full transition of commercialization of the product in the U.S. to us as of August 1, 2020 and a full transition of commercialization of the product in Australia as of November 1, 2020. The ICC Tribunal also awarded us our attorneys' fees and expenses incurred in securing the declaratory judgment as well as the costs incurred by us in the arbitration. Finally, the ICC Tribunal found that SUL breached the SUL Agreement by failing to pay the milestone payment due to us within 30 days of the approval of peramivir for adult use in the European Union and awarded us $5.0 million (plus interest) for this claim. The ICC Tribunal retained jurisdiction for further proceedings for any dispute relating to the return to us of all rights to peramivir in the Territory.

On September 3, 2020, we announced that the U.S. Department of Health and Human Services ("HHS") has exercised its option to purchase an additional 10,000 doses of our antiviral influenza therapy, RAPIVAB (peramivir injection), for $6.9 million. The order is part of a $34.7 million contract the Centers for Disease Control and Prevention awarded in 2018 for the procurement of up to 50,000 doses of RAPIVAB over a five-year period for the Strategic National Stockpile.

Results of Operations (three months ended September 30, 2020 compared to the three months ended September 30, 2019)

For the three months ended September 30, 2020, total revenues were $6.1 million as compared to $1.8 million for the three months ended September 30, 2019. The increase was primarily due to an increase in collaboration revenue under U.S. government development contracts. Revenues in the third quarter of 2020 included $0.3 million of peramivir product revenue from inventory sales to Shionogi and Green Cross, $0.5 million of royalty revenue from Shionogi, Green Cross and SUL associated with sales of peramivir in Japan, Taiwan, and Australia, $0.3 million of deferred revenue amortization related to the Torii Agreement and $3.1 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir. Revenues in the third quarter of 2019 included $0.3 million of peramivir product revenue from inventory sales to Shionogi, $0.5 million of royalty revenue from Shionogi, Green Cross and SUL associated with sales of peramivir in Japan, Taiwan, and Australia, and $0.9 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir.

Research and development ("R&D") expenses increased to $30.2 million for the third quarter of 2020 from $25.1 million for the third quarter of 2019. During the third quarter of 2020, R&D spending increased on our complement-mediated diseases and galidesivir programs, which was offset by a reduction in spend on the ORLADEYO program as we approach commercial launch.

Selling, general and administrative ("SG&A") expenses for the third quarter of 2020 were $17.2 million compared to $11.7 million in the third quarter of 2019. The increase was primarily due to increased spending on commercial activities and medical affairs to support the U.S. commercial launch of ORLADEYO in 2020.

Interest and other income and expense was $(0.3) million in the third quarter of 2020, compared to $0.4 million in the third quarter of 2019. The decrease was primarily due to unrealized foreign currency losses.

Interest expense, which is primarily related to our non-recourse notes issued in conjunction with the non-dilutive RAPIACTA royalty monetization transaction in March 2011 and borrowings under our Second Amended and Restated Senior Credit Facility, was $2.9 million in the third quarter of 2020, compared to $3.0 million in the third quarter of 2019.

Results of Operations (nine months ended September 30, 2020 compared to the nine months ended September 30, 2019)

For the nine months ended September 30, 2020, total revenues were $13.8 million as compared to $9.1 million for the nine months ended September 30, 2019. The increase was primarily due to increased revenue from galidesivir development under U.S. government contracts and amortization of deferred revenue from the Torii Agreement, partially offset by reduced peramivir product sales by our commercial partner in Korea, Green Cross, and lower royalty revenues. Revenues in the first nine months of 2020 included $2.7 million of peramivir product revenue from inventory sales to our commercial partners, $3.5 million of royalty revenue from Shionogi, Green Cross and SUL associated with sales of peramivir in Japan, Taiwan, Korea and the United States, $1.6 million of deferred revenue amortization related to the Torii Agreement and $7.2 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir. Revenues in the first nine months of 2019 included $2.0 million of peramivir product revenue from inventory sales to our commercial partners, $3.5 million of royalty revenue from Shionogi, Green Cross and SUL associated with sales of peramivir in Japan, Taiwan, Korea and the United States, and $3.6 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of galidesivir.

R&D expenses increased to $87.6 million for the first nine months of 2020 from $80.3 million for the first nine months of 2019. The increase in 2020 R&D expenses, as compared to 2019, was primarily due to increased spending on our complement-mediated diseases and galidesivir programs, offset by a reduction in spend on the ORLADEYO program as we approach commercial launch.

The following table summarizes our R&D expenses for the periods indicated (amounts are in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
R&D expenses by program:				
BCX7353	$ 9,947	$ 11,094	$ 36,337	$ 43,501

BCX9930	11,862	9,134	27,305	19,964
Galidesivir	3,035	836	7,395	3,383
BCX9250	231	1,089	2,622	4,611
Peramivir	296	527	1,433	1,731
Other research, preclinical and development costs	4,874	2,440	12,518	7,104
Total R&D expenses	$ 30,245	$ 25,120	$ 87,610	$ 80,294

SG&A expenses for the first nine months of 2020 were $46.9 million compared to $26.6 million in the first nine months of 2019. The increase was primarily due to increased spending on commercial activities and medical affairs to support the U.S. commercial launch of ORLADEYO in 2020 and contingent legal costs associated with our arbitration proceedings.

Interest and other income was $9.0 million in the first nine months of 2020, compared to $1.5 million in the first nine months of 2019. The increase was primarily due to recognition of income related to our arbitration proceedings.

Interest expense, which is primarily related to our non-recourse notes issued in conjunction with the non-dilutive RAPIACTA royalty monetization transaction in March 2011 and borrowings under our Second Amended and Restated Senior Credit Facility, was $8.9 million in the first nine months of 2020, compared to $8.8 million in the first nine months of 2019.

A mark-to-market loss of $0.6 million was recognized in the first nine months of 2020 related to our foreign currency hedge, compared to a mark-to-market loss of $0.5 million in the same period in the prior year, both resulting from changes in the U.S. dollar/Japanese yen exchange rate in the related time periods. In addition, we realized currency exchange gains of $0.7 million and $0.9 million in the first nine months of 2020 and 2019, respectively, associated with the exercise of a U.S. dollar/Japanese yen currency option under our foreign currency hedge.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception, and we expect our 2020 operating expenses to exceed our 2020 revenues. Our operations have principally been funded through public offerings and private placements of equity securities; cash from collaborative and other research and development agreements, including U.S. Government contracts for RAPIVAB and galidesivir; and to a lesser extent, the PhaRMA Notes financing and the Senior Credit Facility, the Amended and Restated Credit Facility, and the Second Amended and Restated Credit Facility. To date, we have been awarded a BARDA/HHS RAPIVAB development contract totaling $234.8 million, which expired on June 30, 2014, a NIAID/HHS galidesivir development contract totaling $45.9 million, which is ongoing, a second NIAID/HHS galidesivir development contract totaling $43.9 million, which is ongoing, and a BARDA/HHS galidesivir development contract totaling $39.1 million, which is also ongoing. The total amount of NIAID/HHS and BARDA/HHS galidesivir funding obligated under awarded options is $52.2 million and $20.6 million, respectively. We may issue securities through private placement transactions or registered public offerings pursuant to a registration statement filed with the SEC. On June 1, 2020, we issued 22,044,447 shares of common stock to the public at a purchase price of $4.50 per share and pre-funded warrants to purchase 3,511,111 shares of common stock at a purchase of $4.49 per pre-funded warrant, for total net proceeds to us of $107.7 million after deducting underwriting discounts and commissions and other offering expenses payable by us. The pre-funded warrants are immediately exercisable and have an exercise price of $0.01 per share, which is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, or similar events affecting our common stock and also upon any distributions of assets to our stockholders. In addition to the above, we have previously received funding from other sources, including other collaborative and other research and development agreements; government grants; equipment lease financing; facility leases; research grants; and interest income on our investments.

As of September 30, 2020, we had net working capital of $50.7 million, a decrease of approximately $21.3 million from $72.0 million at December 31, 2019. The decrease in working capital was principally due to our normal operating expenses associated with the development of our product candidates, partially offset by the June 2020 public offering of our common stock and pre-funded warrants to purchase our common stock. Our principal sources of liquidity at September 30, 2020 were approximately $96.5 million in cash and cash equivalents and approximately $49.8 million in investments considered available-for-sale. We anticipate our cash and investments will fund our planned operations through the second quarter of 2021.

We intend to contain costs and cash flow requirements by closely managing our third-party costs and headcount, leasing scientific equipment and facilities, contracting with other parties to conduct certain research and development projects and using consultants. We expect to incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities and begin to build a commercial infrastructure. We may incur additional expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical programs advance through later stages of development. The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of our credit exposure. We have not realized any significant losses on our investments.

We plan to finance our needs principally from the following:

- lease, royalty or loan financing and future public or private equity or debt financing;
- our existing capital resources and interest earned on that capital;
- payments under existing and executing new contracts with the U.S. Government; and
- payments under current or future collaborative and licensing agreements with corporate partners.

As our programs continue to advance, our costs will increase. Our current and planned clinical trials, plus the related development, manufacturing, regulatory approval process requirements and additional personnel resources and testing required for the continuing development of our product candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our product candidates, the amount and timing of funding we receive from existing U.S. Government contracts for galidesivir, the amount of funding or assistance, if any, we receive from new U.S. Government contracts or other new partnerships with third parties for the development and/or commercialization of our product candidates, the progress and results of our current and proposed clinical trials for our most advanced product candidates, the progress made in the manufacturing of our lead product candidates, commercialization of our products, and the overall progression of our other programs. The impact of the ongoing COVID-19 pandemic on one or more of the foregoing factors could negatively affect our expenses, revenues and cash utilization rate.

With the funds available at September 30, 2020, we believe our financial resources will be sufficient to fund our planned operations through the second quarter of 2021. We have sustained operating losses for the majority of our corporate history and expect that our 2020 expenses will exceed our 2020 revenues. We expect to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations. Accordingly, our planned operations raise doubt about our ability to continue as a going concern throughout 2021. Our liquidity needs will be largely determined by the success of operations in regard to the progression of our product candidates in the future. We also may consider other plans to fund operations through 2021 including: (1) securing or increasing U.S. Government funding of our programs, including obtaining procurement contracts; (2) out-licensing rights to certain of our products or product candidates, pursuant to which we would receive cash milestone payments; (3) raising additional capital through equity or debt financings or from other sources, including royalty or other monetization transactions; (4) obtaining additional product candidate regulatory approvals, which would generate revenue, milestone payments and cash flow; (5) reducing spending on one or more research and development programs, including by discontinuing development; and/or (6) restructuring operations to change our overhead structure. We may issue securities, including common stock, preferred stock, depositary shares, purchase contracts, warrants, debt securities and units, through private placement transactions or registered public offerings. Our future liquidity needs, and ability to address those needs, will largely be determined by the success of our product candidates, the timing, scope and magnitude of our commercial expenses and key development and regulatory events and our decisions in the future.

Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- our ability to perform under our government contracts and receive reimbursement thereunder, and receive stockpiling procurement contracts;
- the magnitude of work under our government contracts;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships or government contracts;
- our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;
- the extent to which our partners, including governmental agencies, will share in the costs associated with the development of our programs or run the development programs themselves;
- our ability to negotiate favorable development and marketing strategic alliances for certain product candidates or a decision to build or expand internal development and commercial capabilities;
- successful commercialization of marketed products by either us or a partner;
- the scope and results of preclinical studies and clinical trials to identify and develop product candidates;
- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our product candidates to support our preclinical research and clinical trials;
- increases in personnel and related costs to support the development and commercialization of our product candidates;
- the scope of manufacturing of our drug substance and product candidates required for future NDA filings;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- post-approval commitments for RAPIVAB and other products that receive regulatory approval; and
- the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

The impact of the ongoing COVID-19 pandemic on one or more of the foregoing factors could negatively affect our capital requirements and the availability of funds to finance those requirements.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates, and we may seek to raise capital in the future. Additional funding, whether through equity or debt financings, royalty or other monetization transactions, collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and existing government contracts specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale back or eliminate certain of our research and development programs. Our future working capital requirements, including the need for additional working capital, will be largely determined by the advancement of our portfolio of product candidates as well as the rate of reimbursement by U.S. Government agencies of our galidesivir expenses and any future decisions regarding the future of the RAPIVAB and galidesivir programs, including those relating to stockpiling procurement. More specifically, our working capital requirements will be dependent on the number, magnitude, scope and timing of our development programs; regulatory approval of our product candidates; obtaining funding from collaborative partners; the cost, timing and outcome of regulatory reviews, regulatory investigations, and changes in regulatory requirements; the costs of obtaining patent protection for our product candidates; the timing and terms of business development activities; the rate of technological advances relevant to our operations; the efficiency of manufacturing processes developed on our behalf by third parties; the timing, scope and magnitude of commercial spending, and the level of required administrative support for our daily operations.

The restrictive covenants contained in the Second Amended and Restated Senior Credit Facility could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial without the lender's permission or without repaying all Second Amended and Restated Senior Credit Facility obligations. These covenants limit our ability to, among other things, convey, sell, lease, license, transfer or otherwise dispose of certain parts of our business or property; change the nature of our business; liquidate or dissolve; enter into certain change in control or acquisition transactions; incur or assume certain debt; grant certain types of liens on our assets; modify, liquidate or transfer assets in certain collateral accounts; pay dividends or make certain distributions to our stockholders; make certain investments; enter into material transactions with affiliates; and modify existing debt or collaboration arrangements. A breach of any of these covenants could result in an event of default under the Second Amended and Restated Senior Credit Facility.

Financial Outlook for 2020

With the additional capital raised in the second quarter of 2020 and the safety and proof-of-concept data generated to date with BCX9930 in PNH patients, we are investing in accelerated development of BCX9930 and expect full year 2020 net operating cash use to be in the range of $150 to $165 million, and our operating expenses to be in the range of $180 to $195 million. Our operating expense range excludes equity-based compensation expense due to the difficulty in accurately projecting this expense as it is significantly impacted by the volatility and price of our stock, as well as vesting of our outstanding performance-based stock options. Our operating cash forecast excludes any impact of our royalty monetization, hedge collateral posted or returned, and any other non-routine cash outflows or inflows. Our ability to remain within our operating expense and operating cash target ranges is subject to multiple factors, including unanticipated or additional general development and administrative costs and other factors described under the Risk Factors located elsewhere in this report.

Off-Balance Sheet Arrangements

As of September 30, 2020, we do not have any unconsolidated entities or off–balance sheet arrangements.

Critical Accounting Policies

We have established various accounting policies that govern the application of U.S. GAAP, which were utilized in the preparation of our consolidated financial statements. Certain accounting policies involve significant judgments and assumptions by management that have a material impact on the carrying value of certain assets and liabilities. Management considers such accounting policies to be critical accounting policies. The judgments and assumptions used by management are based on historical experience and other factors, which are believed to be reasonable under the circumstances. Because of the nature of the judgments and assumptions made by management, actual results could differ from these judgments and estimates, which could have a material impact on the carrying values of assets and liabilities and the results of operations.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Inventory

Our inventories consist of peramivir finished goods and work in process, which are valued at the lower of cost or net realizable value using the first-in, first-out (i.e., FIFO) method. Cost includes materials, labor, overhead, shipping and handling costs. Our inventories are subject to expiration dating. We regularly evaluate the carrying value of our inventories and provide valuation reserves for any estimated obsolete, short-dated or unmarketable inventories. In addition, we may experience spoilage of our raw materials and supplies. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. In connection with the FDA approval of RAPIVAB and other regulatory approvals, we began capitalizing costs associated with the production of peramivir inventories.

Accrued Expenses

We enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. We record liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organizations ("CROs") in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and product candidates; and
- professional fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

Revenue Recognition

Collaborative and Other Research and Development Arrangements and Royalties

We recognize revenue when we satisfy a performance obligation by transferring promised goods or services to a customer. Revenue is measured at the transaction price that is based on the amount of consideration that we expect to receive in exchange for transferring the promised goods or services to the customer. The transaction price includes estimates of variable consideration to the extent it is probable that a significant reversal of revenue recognized will not occur.

We have collaboration and license agreements with a number of third parties as well as research and development agreements with certain government entities. Our primary sources of revenue are license, service, royalty and product sale revenues from these collaborative and other research and development arrangements.

Revenue from license fees, royalty payments, milestone payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations or we have completed the performance obligations under the terms of the agreement.

Arrangements that involve the delivery of more than one performance obligation are initially evaluated as to whether the intellectual property licenses granted by us represent distinct performance obligations. If they are determined to be distinct, the value of the intellectual property licenses would be recognized up-front while the research and development service fees would be recognized as the performance obligations are satisfied. Variable consideration is assessed at each reporting period as to whether it is not subject to significant future reversal and, therefore, should be included in the transaction price at the inception of the contract. If a contract includes a fixed or minimum amount of research and development support, this also would be included in the transaction price. Changes to collaborations, such as the extensions of the research term or increasing the number of targets or technology covered under an existing agreement, are assessed for whether they represent a modification or should be accounted for as a new contract. For contracts with multiple performance obligations, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which we separately sell the products or services. If a standalone selling price is not directly observable, then we estimate the standalone selling price considering market conditions and entity-specific factors. Analyzing the arrangement to identify performance obligations requires the use of judgment, and each may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not probable at the inception of the agreement; and (ii) we have a right to payment. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss rather than as a reduction in expenses. Under our contracts with BARDA/HHS and NIAID/HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

Under certain of our license agreements, we receive royalty payments based upon our licensees' net sales of covered products. Royalties are recognized at the later of when (i) the subsequent sale or usage occurs, or (ii) the performance obligation to which some or all of the sales-based or usage-based royalty has been satisfied.

Product Sales

Our principal sources of product sales are sales of peramivir to our licensing partners and sales of RAPIVAB to the U.S. Department of Health and Human Services under our procurement contract. We recognize revenue for sales when the customer obtains control of the product, which generally occurs upon delivery.

Contract Balances

The timing of revenue recognition, billings and cash collections results in billed accounts receivable, unbilled receivables (contract assets) and deferred revenue and billings in excess of revenue recognized (contract liabilities) on the Consolidated Balance Sheets.

Contract assets - Our long-term contracts are billed as work progresses in accordance with the contract terms and conditions, either at periodic intervals or upon achievement of certain milestones. Often this results in billing occurring subsequent to revenue recognition, resulting in contract assets. Contract assets are generally classified as current assets in the Consolidated Balance Sheets.

Contract liabilities - We often receive cash payments from customers in advance of our performance, resulting in contract liabilities. These contract liabilities are classified as either current or long-term in the Consolidated Balance Sheets based on the timing of when we expect to recognize the revenue.

Contract Costs

We may incur direct and indirect costs associated with obtaining a contract. Incremental contract costs that we expect to recover are capitalized and amortized over the expected term of the contract. Non-incremental contract costs and costs that we expect to recover are expensed as incurred.

Research and Development Expenses

Our research and development costs are charged to expense when incurred. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits; manufacturing costs; clinical, regulatory, and toxicology services performed by CROs; materials and supplies and overhead allocations consisting of various administrative and facilities related costs. Most of our manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by us over the service periods specified in the contracts and estimates are adjusted, if required, based upon our on-going review of the level of services actually performed.

Additionally, we have license agreements with third parties, such as the Albert Einstein College of Medicine of Yeshiva University, Industrial Research, Ltd. and the University of Alabama at Birmingham ("UAB"), which require fees related to sublicense agreements or maintenance fees. We expense sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. We expense maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments paid to our academic partners upon receipt of consideration from various commercial partners, and other consideration to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

We group our R&D expenses into two major categories: direct external expenses and indirect expenses. Direct expenses consist of compensation for R&D personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidate, conduct and manage clinical trials, as well as other costs related to our clinical and preclinical studies. These costs are accumulated and tracked by active program. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and other overhead of our research and development efforts. These costs apply to work on non-active product candidates and our discovery research efforts.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in our Consolidated Statements of Comprehensive Loss based on their fair values. Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award. Determining the appropriate fair value model and the related assumptions for the model requires judgment, including estimating the life of an award, the stock price volatility, and the expected term. We utilize the Black-Scholes option-pricing model to value our awards and recognize compensation expense on a straight-line basis over the vesting periods. The estimation of share-based payment awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. In addition, we have outstanding performance-based stock options for which no compensation expense is recognized until "performance" has occurred. Significant management judgment is also required in determining estimates of future stock price volatility and forfeitures to be used in the valuation of the options. Actual results, and future changes in estimates, may differ substantially from our current estimates.

Currency Hedge Agreement

In connection with our issuance of the PhaRMA Notes, we entered into a foreign Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar.

The Currency Hedge Agreement does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in our Consolidated Statements of Comprehensive Loss. Mark to market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by generally accepted accounting principles ("U.S. GAAP"). We are also required to post collateral in connection with the mark to market adjustments based on defined thresholds. As of September 30, 2020, no collateral was posted under the agreement.

Tax

We account for uncertain tax positions in accordance with U.S. GAAP. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance against all potential tax assets, due to uncertainties in our ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of taxable income in each of the jurisdictions in which we operate and the period over which our deferred tax assets will be recoverable.

Information Regarding Forward-Looking Statements

This filing contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created in Section 21E. All statements other than statements of historical facts contained in this filing are forward-looking statements. These forward-looking statements can generally be identified by the use of words such as "may," "will," "intends," "plans," "believes," "anticipates," "expects," "estimates," "predicts," "potential," the negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

- the impact of the ongoing COVID-19 pandemic on all aspects of our business, including without limitation delays, stoppages, difficulties and increased expenses with respect to our and our partners' development, regulatory and supply chain operations, or on our ability to access the capital or credit markets to finance our operations;
- the preclinical development, clinical development, commercialization, or post-marketing studies of our product candidates and products, including ORLADEYO, BCX9930, BCX9250, peramivir, galidesivir, and early stage discovery programs;
- the potential funding from our contracts with NIAID/HHS and BARDA/HHS for the development of galidesivir;
- the potential for government stockpiling orders of peramivir and galidesivir, additional regulatory approvals of peramivir, or milestones, royalties or profit from sales of peramivir by us or our partners;
- the potential use of peramivir as a treatment for H1N1, H5N1, and H7N9 or other strains of influenza;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- our ability to establish and maintain collaborations or out-license rights to our product candidates;
- the outcome, cost and timing of any resolution of disputes and legal proceedings, including but not limited to the dispute with our partner SUL;
- plans, programs, progress and potential success of our collaborations, including Mundipharma for mundesine, Torii for ORLADEYO in Japan and Shionogi and Green Cross for peramivir in their territories;
- our and MDCP's ability to satisfy obligations under our Second Amended and Restated Senior Credit Facility;
- Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes;
- the Currency Hedge Agreement entered into by us in connection with the issuance by Royalty Sub of the PhaRMA Notes;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;

- our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, revenues, capital requirements, annual cash utilization, and our needs for additional financing;
- our ability to continue as a going concern;
- the timing or likelihood of regulatory filings or regulatory agreements, deferrals, and approvals;
- the timing or likelihood of entering into a U.S. government stockpile order and our ability to execute any such order;
- our plans and ability to raise additional capital to fund our operations or repay our recourse debt obligations;
- our ability to comply with the covenants as set forth in the agreements governing our debt obligations;
- our financial performance;
- the timing and success of our anticipated commercialization of ORLADEYO in the U.S. and elsewhere; and
- competitive companies, technologies and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors." Any forward-looking statement reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are subject to interest rate risk on our investment portfolio and borrowings under our fixed-interest rate PhaRMA Notes and our variable-interest rate Second Amended and Restated Senior Credit Facility. The interest rate applicable to our borrowings under the PhaRMA Notes is fixed at 14.0%, and the Second Amended and Restated Senior Credit Facility bears a floating interest rate based on LIBOR. Increases in interest rates could therefore increase the associated interest payments that we are required to make on the Second Amended and Restated Senior Credit Facility. As of September 30, 2020, our Second Amended and Restated Senior Credit Facility had an interest rate of 8.5%.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point increase or decrease in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments, including our borrowings, but may affect our future earnings and cash flows. We generally have the ability to hold our fixed-income investments to maturity and therefore do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities.

Foreign Currency Risk

The majority of our transactions and the greatest magnitude of these transactions occur in U.S. dollars and we do not have significant operating subsidiaries or significant investments in foreign countries as of September 30, 2020. Therefore, we are not subject to significant foreign currency exchange risk in our normal operations.

Item 4. Controls and Procedures

We maintain a set of disclosure controls and procedures that are designed to ensure that information relating to BioCryst Pharmaceuticals, Inc. required to be disclosed in our periodic filings under the Exchange Act is recorded, processed, summarized and reported in a timely manner under the Exchange Act. We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2020, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer of the Company, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. *RISK FACTORS*

An investment in our stock involves risks. You should carefully read this entire report and consider the following uncertainties and risks, which may adversely affect our business, financial condition or results of operations, along with all of the other information included in our other filings with the SEC, before deciding to buy our common stock.

Risks Relating to Our Business

Risks Relating to COVID-19

Our business, operations, clinical development or commercialization plans and timelines, and access to capital could be adversely affected by the effects of the recent COVID-19 pandemic on us or on third parties with whom we conduct business, including without limitation our development partners, manufacturers, CROs, and others, as well as on the regulatory and government agencies with whom we work.

The COVID-19 pandemic has spread to multiple countries around the world, is affecting the United States and global economies, and may cause significant disruptions to our business, operations, and clinical development or commercialization plans and timelines, as well as the business and operations of third parties with whom we conduct business. For example, quarantines, shelter-in-place and similar government orders have impacted and may continue to impact, among other things: (1) our personnel and those of third parties on whom we rely, including our development partners (such as Torii), manufacturers, CROs, and others; (2) the conduct of our current and future clinical trials; and (3) the operations of the FDA, EMA, PMDA and other health and governmental authorities, which could result in delays of reviews and approvals.

If our operations or those of third parties with whom we conduct business are impaired or curtailed as a result of these events, the development and commercialization of our products and product candidates could be stopped or delayed, or the costs of such development and commercialization activities could increase, any of which could have a material adverse impact on our business. For example, if interruptions related to COVID-19 were to impair our or Torii's ability to perform under the Torii Agreement to complete our regulatory interactions in Japan, including with respect to the pending Japanese NDA with respect to ORLADEYO for the treatment of HAE, then the timing and success of our development and commercialization of ORLADEYO in Japan could be severely impacted.

Our suppliers or other vendors may be unable to meet their obligations to us or perform their services as expected as a result of the COVID-19 pandemic or other health epidemics. In such circumstances, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Such delays could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

In addition, our clinical trials may be affected by the COVID-19 pandemic. For example, the acceleration of COVID-19 has slowed startup of the inadequate C5 responder cohorts in our complement oral Factor D inhibitor program and, as a result, delayed the reporting of related data. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city, or state could adversely impact our clinical trial operations.

If global health concerns prevent the FDA, EMA, PMDA or other regulatory authorities from conducting their inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, EMA, PMDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business and clinical development plans and timelines.

We have implemented work-from-home policies for our employees, which may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

The spread of COVID-19, which has caused a broad impact globally, may also materially affect our access to capital. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the pandemic could result in significant disruption of global financial markets, reducing our ability to access the equity or debt capital markets or obtain other sources of capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. These effects could be material, and we will continue to monitor the COVID-19 situation closely. We do not yet know the full extent and magnitude of the impacts that COVID-19 has had or will have on our business, on the healthcare system, or on the global economy. In addition, the COVID-19 pandemic could have the effect of heightening many of the other risks described below.

General Operating and Liquidity Risks

We have incurred losses since our inception, expect to continue to incur such losses, and may never be profitable.

Since our inception, we have not achieved sustained profitability. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts and commercial activities progress. We expect that such losses will fluctuate from quarter to quarter and that losses and fluctuations may be substantial. To become profitable, we, or our collaborative partners, must successfully manufacture and develop product candidates, receive regulatory approval, and successfully commercialize and/or enter into profitable commercialization arrangements with other parties. It could be several years, if ever, before we receive significant revenue from any current or future license agreements or revenues directly from product sales.

Because of the numerous risks and uncertainties associated with developing our product candidates and their potential for commercialization, we are unable to predict the extent of any future losses. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We may not be able to continue as a going concern if we do not obtain additional capital.

We have sustained operating losses for the majority of our corporate history and expect that our 2020 expenses will exceed our 2020 revenues. We expect to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations.

Our liquidity needs will be largely determined by the success of operations in regard to the progression of our product candidates in the future. Our plans to alleviate the doubt regarding our ability to continue as a going concern primarily include controlling the timing and spending on our research and development programs, raising additional funds through equity financings, and commercializing approved product candidates. We also may consider other plans to fund operations including: (1) securing or increasing U.S. Government funding of our programs, including obtaining additional and delivering on procurement contracts; (2) out-licensing rights to certain of our products or product candidates, pursuant to which we would receive cash milestone payments and/or royalties; (3) raising additional capital through equity or debt financings or from other sources, including royalty or other monetization transactions; (4) obtaining additional product candidate regulatory approvals, which would generate revenue, milestones and cash flow; (5) reducing spending on research and development programs, including by discontinuing and suspending development; and/or (6) restructuring operations to change our overhead structure.

There can be no assurance that any of our plans will be successful or that additional capital will be available to us on reasonable terms, or at all, when needed. If we are unable to obtain sufficient additional capital, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether or file for bankruptcy.

Risks Relating to Drug Development and Commercialization

Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process, and to receive regulatory approval for the commercial sale of our products.

To receive the regulatory approvals necessary for the commercial sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The development process and related regulatory process are complex and uncertain. The preclinical and clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of drug development, including failure to demonstrate efficacy and safety, the occurrence of adverse events that are severe or medically or commercially unacceptable, our or our partners' failure to comply with trial protocols, applicable regulatory requirements, and industry standards, or a determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or be approved in accordance with our development plans or at all. We cannot guarantee that any preclinical studies and clinical trials will be conducted as planned or completed on schedule, if at all, or that the results of such trials will be sufficient to support regulatory approval for our product candidates.

Progression of our product candidates through the clinical development process is dependent upon our trials indicating that our product candidates have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the clinical trial protocols. Failure to achieve any of these endpoints in any of our programs, including ORLADEYO, BCX9930, BCX9250, galidesivir, and our other rare disease product candidates, could result in delays in or modifications to our trials or require the performance of additional unplanned trials. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Product candidates that initially show promise in clinical or preclinical testing could later be found to cause undesirable or unexpected side effects that could result in delays in the development of our product candidates, significant unexpected costs, or the termination of programs. The development plans for our product candidates, including our clinical trials, may not be adequately designed or executed, which could negatively affect the outcome and analysis of study results. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show favorable results in clinical trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have reasonable commercial potential.

Undesirable or inconclusive data in our pre-clinical studies and clinical trials or side effects in humans could result in the FDA or foreign regulatory authorities (including, e.g., the EMA, the Japanese Ministry of Health, Labor & Welfare ("MHLW") or the MHRA) refusing to approve a product candidate for any targeted indications or imposing restrictions or warnings that could impact development or the ultimate commercial viability of a product candidate. In addition, the FDA or foreign regulatory authorities may determine that study data from our product candidates necessitates additional studies or study designs which differ from our planned development strategy, and such regulatory authorities may also require patient monitoring and testing or may implement restrictions or other conditions on our development activities, any of which could materially impact the cost and timing of our planned development strategy. We, our partners, the FDA, or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks.

Our ability to successfully complete the clinical development process is dependent upon many factors, including but not limited to:

- our or our partners' ability to secure suitable clinical sites and investigators and to enroll and maintain an adequate number of patients on a timely basis or at all;
- patients that enroll in a clinical trial may not comply with the clinical trial protocol or maintain contact with investigators to provide complete data during and after treatment;
- our product candidates may not prove to be either safe or effective or may produce unfavorable or inconclusive results;
- we or our partners may decide, or be required by regulatory authorities, to suspend or terminate clinical research for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, noncompliance with regulatory requirements or their standards of conduct, or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- regulatory authorities may disagree with our or our partners' clinical trial protocols or our or their interpretation of data from preclinical studies and clinical trials;
- clinical protocols or study procedures may not be adequately designed or followed by the investigators;

- formulation improvements may not work as expected, which could negatively impact commercial demand for our product candidates;
- regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we or our partners enter into agreements for clinical and commercial supplies;
- the supply or quantity of raw materials or manufactured product candidates or other materials necessary to conduct development activities may be insufficient, inadequate, or unavailable at an acceptable cost, and we or our partners may experience interruptions in supply;
- our or our partners' development plans may be delayed or changed as a result of changes in development strategy, the impact of new or different regulations, requirements, and guidelines, or other unexpected events or conditions;
- the cost of pre-clinical studies and clinical trials may be greater than we anticipate;
- we or our third-party contractors, including those manufacturing our product candidates or components or ingredients thereof, or conducting clinical trials or laboratory testing on our or our partners' behalf, may fail to comply with regulatory requirements and industry standards or meet contractual obligations in a timely manner or at all; and
- the impact of the COVID-19 pandemic on one or more of the foregoing factors.

Clinical trials are lengthy and expensive. Many of the factors listed above could result in increased clinical development costs or longer clinical development times for any of our programs. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet we cannot be certain that the tests and trials will ever result in the commercial sale of a product. Even if we or our partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner, may not receive regulatory approval for the product candidates, in which case we would be unable to generate any revenues from product sales or licensing arrangements, or any product candidate, if approved, may be subject to restrictions on labeling, marketing, distribution, prescribing, and use, which could adversely impact the sales of such product.

If our development collaborations with third parties, such as our development partners, contractors and contract research organizations, fail, the development of our product candidates will be delayed or stopped.

We rely heavily upon third parties for many important stages of our product candidate development, including but not limited to:

- discovery of natural proteins that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;
- execution of certain pharmacology preclinical studies and late-stage development for our compounds and product candidates;
- management of our Phase 1, 2 and 3 clinical trials, including medical monitoring, laboratory testing, and data management;
- execution of toxicology studies that may be required to obtain approval for our product candidates;
- formulation improvement strategies and methods;
- manufacturing the starting materials and drug substance required to formulate our products and the product candidates to be used in our clinical trials, toxicology studies and any potential commercial product; and
- management of certain regulatory interactions outside of the United States.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license enzyme targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, our drug development efforts would suffer. Similarly, if the contract research organizations or third-party contractors that conduct our initial or late-stage clinical trials, conduct our toxicology or other studies, manufacture our starting materials, drug substance and product candidates, provide laboratory testing or other services in connection with our clinical trials, or assist with our regulatory function breach their obligations to us, perform their services inconsistent with industry standards, or fail to comply with regulatory requirements, this would delay or prevent both the development of our product candidates and the availability of any potential commercial product.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to applicable FDA current Good Laboratory Practices, current Good Manufacturing Practices ("cGMP") and current Good Clinical Practices, and comparable foreign standards. We do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed. If any of the foregoing risks are realized, our business, financial condition and results of operations could be materially adversely affected.

If we fail to obtain additional financing or acceptable partnership arrangements, we may be unable to complete the development and commercialization of our product candidates or continue operations.

As our programs advance, our costs are likely to increase. Our current and planned discovery, development, approval, and commercialization efforts will require significant capital. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including: our ability to obtain regulatory approval for and successfully commercialize our product candidates, including ORLADEYO, BCX9930, BCX9250, and galidesivir; our ability to raise additional capital; the amount of funding we receive from partnerships with third parties for the development and commercialization of our product candidates (including, our collaborations with Torii, BARDA/HHS and NIAID/HHS); the commercial success of peramivir achieved by our partners; the amount or profitability of any orders for peramivir or galidesivir by any government agency or other party; the progress and results of our current and proposed clinical trials for our product candidates; and the progress made in the manufacture of our lead products and the progression of our other programs.

In order to continue future operations, progress our drug development programs, and commercialize our current product candidates, we will be required to raise additional capital. In addition to seeking strategic partnerships, transactions and government funding, we may access the equity or debt markets, incur additional borrowings, or seek other sources of funding to meet liquidity needs at any time. Additional funding, whether through additional sales of securities, additional borrowings, royalty or other monetization transactions, collaborative arrangements with partners, including corporate partners such as Torii and governmental agencies such as BARDA/HHS or NIAID/HHS, or from other sources, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of our currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. Additional borrowings may subject us to more restrictive covenants than are currently applicable to us under our Second Amended and Restated Senior Credit Facility. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds or lack of an acceptable partnership may require us to delay, scale-back or eliminate certain of our research and development programs.

Our ability to raise additional capital when needed or at all may be limited and may greatly depend upon the success of our current drug development programs, including the progress, timeline and ultimate outcome of the development programs (including but not limited to formulation progress, long-term human safety studies, and carcinogenicity, drug-drug interaction, toxicity, or other required studies) for ORLADEYO, BCX9250 for the treatment of FOP, BCX9930 for diseases of the complement system, our broad-spectrum antiviral program, including galidesivir, and other rare disease product candidates, as well as any post-approval studies for RAPIVAB. In addition, constriction and volatility in the equity and debt markets, including as a result of the impacts of COVID-19, may restrict our future flexibility to raise capital when such needs arise. Furthermore, we have exposure to many different industries, financing partners and counterparties, including commercial banks, investment banks and partners (which include investors, licensing partners, and the U.S. Government) which may be unstable or may become unstable in the current economic and political environment, including as a result of the impacts of COVID-19. Any such instability may impact these parties' ability to fulfill contractual obligations to us or they might limit or place burdensome conditions upon future transactions with us. Also, it is possible that suppliers may be negatively impacted. Any such unfavorable outcomes in our current programs or unfavorable economic conditions could place severe downward pressure on the price of our common stock and may decrease opportunities to raise capital in the capital or credit markets, and further could reduce the return available on invested corporate cash, which, if severe and sustained, could have a material and adverse impact on our results of operations and cash flows and limit our ability to continue development of our product candidates.

If we or our partners do not obtain and maintain governmental approval for our product candidates, we or our partners will not be able to commercialize and sell these potential products, which would significantly harm our business because we will receive no revenue.

We or our partners must obtain regulatory approval before marketing or selling our products. If the FDA or a comparable foreign regulatory authority delays or denies regulatory approval of one of our product candidates, or revokes approval of a previously approved product, we would be unable to market or sell the product in the applicable jurisdiction and would not receive revenue from sales or licensing arrangements related thereto, which could have a material and adverse impact on our business.

The process of preparing for and obtaining regulatory approval in any jurisdiction may be lengthy and expensive, and approval is never certain. Because of the risks and uncertainties inherent to the development process, including risks and uncertainties related to the impact of COVID-19, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. As discussed under "Risk Factors—Risks Relating to Our Business—Risks Relating to Drug Development and Commercialization—Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process, and to receive regulatory approval for the commercial sale of our products," we or our partners may experience any number of unfavorable outcomes during or as a result of pre-clinical studies and clinical trials that could delay or prevent regulatory approval of our product candidates, or negatively impact our management's credibility, our value and our operating results.

Even if the FDA or foreign regulatory authorities approve a product candidate, the approval may limit the indicated uses for a product candidate, impose other restrictions on the product candidate, and/or may require post-approval studies that could impair the commercial viability of a product candidate. If we receive approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

- adverse drug experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

Our failure to comply with existing or future regulatory requirements for regulatory approval, or our loss of, or changes to, previously obtained approvals, could impair our ability to generate any revenues from product sales or licensing arrangements, which could have a material adverse effect on our business, financial condition, and results of operations.

We focus on rare diseases, which may create additional risks and challenges.

Because we focus on developing drugs as treatments for rare diseases, we may seek orphan drug, breakthrough therapy or fast track designations for our product candidates in the United States or the equivalent designations elsewhere in the world. Often, regulatory authorities have broad discretion in determining whether or not to grant such designations. We cannot guarantee that our product candidates will receive orphan drug status from the FDA or equivalent designations from other regulatory authorities. We also cannot guarantee that we will receive breakthrough therapy, fast track, or equivalent designations, which provide certain potential benefits such as more frequent meetings with the applicable regulatory authorities to discuss development plans, intensive guidance on efficient drug development programs, and potential eligibility for rolling review or priority review. Even if we are successful in obtaining any such designations for our product candidates, such designations may not lead to faster development or regulatory review or approval and do not increase the likelihood that our product candidates will receive marketing approval. For instance, although BCX9930 for PNH and ORLADEYO for HAE prophylaxis have received Fast Track and Orphan Drug designations from the FDA, and ORLADEYO has also received Sakigake designation from the PMDA and Promising Innovative Medicine designation from the MHRA, as well as orphan drug status from the EMA and the MHLW, we may not experience a faster development, review or approval process compared to the conventional process in the relevant jurisdictions. We may not be able to obtain or maintain these designations for ORLADEYO, BCX9930 or other product candidates that receive them, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our product candidates or compete with such competitors, which may adversely impact our business, financial condition or results of operations.

The commercial viability of any approved product could be compromised if the product is less effective than expected, causes undesirable side effects that were not previously identified, or fails to achieve market acceptance within the medical community.

If after obtaining regulatory approval of a product we or others discover that it is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of, or impose marketing or manufacturing restrictions on, the product, or require us or our partners to create a medication guide outlining the risks of unidentified side effects for distribution to patients;

- we or our partners may be required to recall the product, change the way the product is administered, conduct additional clinical trials, or be subject to civil or criminal penalties; and
- the product may become less competitive and our reputation may suffer.

Even after receiving regulatory approval, any product could fail to gain sufficient, or even any, market acceptance by physicians, patients, third party payors, health authorities and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. If an approved product does not achieve an adequate level of market acceptance, it may not generate significant revenues. The occurrence of any of the foregoing could have a material and adverse impact on our business.

If we fail to successfully commercialize or establish collaborative relationships to commercialize certain of our product candidates, or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.

Our business strategy is to increase the asset value of our product candidate portfolio. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third-party relationships could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our product candidates.

Currently, we have established collaborative relationships with Torii for the commercialization of ORLADEYO in Japan, with each of Shionogi and Green Cross for the development and commercialization of peramivir, and with Mundipharma for the development and commercialization of Mundesine (forodesine). The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory commercial, regulatory or clinical results, including post approval clinical commitments, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration, such as the recent arbitration proceeding between us and SUL, which could result in substantial costs and divert the attention of our management;
- we do not have day to day control over the activities of our partners and have limited control over their decisions;
- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our product candidates, obtain regulatory approvals and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- we or our partners may not devote sufficient capital or resources towards our product candidates; and
- we or our partners may not comply with applicable government regulatory requirements.

If we or our partners fail to fulfill our responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development or commercialization of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our product candidates would severely affect our business, because if our product candidates do not progress through the development process or reach the market in a timely manner, or at all, we may not receive any revenues from product sales or licensing arrangements.

The results of our partnership with Torii may not meet our current expectations.

We have an agreement with Torii for the development and commercialization of ORLADEYO in Japan (the "Torii Agreement"). We do not have a history of working with Torii and cannot predict the success of this collaboration. Our ability to realize the expected benefits of this collaboration, including with respect to the receipt or amounts of potential milestone or royalty payments, is subject to a number of risks, including that applicable regulatory agencies may not provide adequate regulatory clearances or reimbursement approvals on a timely basis or at all, the commercial potential of ORLADEYO may not meet our current expectations, we or Torii may fail to comply with our respective obligations under the Torii Agreement, and third parties may fail to perform their obligations to us on a timely basis or at all.

The Torii Agreement provides for a potential milestone payment depending on the receipt and timing of regulatory approval and contingent upon receipt of a reimbursement price approval from Japan's National Health Insurance system in excess of the threshold specified in the Torii Agreement, either of which we may not receive on a timely basis or at all. The Torii Agreement also provides that we will be entitled to receive tiered royalty payments, the amounts of which will depend upon the amount of annual net sales of ORLADEYO in Japan during each calendar year, whether ORLADEYO maintains its Sakigake designation, and other factors. We remain responsible for regulatory activities with respect to ORLADEYO in Japan for one year after the first commercial sale. We expect to use third parties to satisfy many of our obligations under the Torii Agreement, including but not limited to our regulatory and other responsibilities in Japan. If our interactions, or those of our third party agents, are unsuccessful, we could fail to meet our obligations under the Torii Agreement, fail to receive regulatory approval of ORLADEYO on a timely basis or at all, receive approval of ORLADEYO on a narrower scope than currently anticipated, or fail to receive reimbursement authorization in excess of the specified threshold, which could negatively impact the commercial success and the partnership, impact the economic benefit expected or require additional development of ORLADEYO.

Torii may terminate the Torii Agreement under certain limited circumstances, including the receipt of notice that certain additional development activities are required for regulatory approval of ORLADEYO, if regulatory approval of ORLADEYO is not received prior to December 31, 2022, or upon one year's written notice after the sixth anniversary of the first commercial sale of ORLADEYO in Japan. If the Torii Agreement is terminated in connection with these provisions, we will no longer be entitled to receive any milestone or royalty payments thereunder, which could have a material adverse impact on our business and results of operations.

Torii will have sole control over and decision-making authority with respect to commercialization activities for ORLADEYO for the prevention of HAE attacks in Japan, subject to oversight from a joint steering committee. Therefore, our receipt of, and the amounts of, any royalty payments under the Torii Agreement are dependent upon Torii's successful performance of such commercialization activities. In addition, competitive products and variations in patient demand, prescription levels, reimbursement determinations or other factors may limit the commercial potential of ORLADEYO in Japan, which could materially reduce the amount of any royalties we would be entitled to receive under the Torii Agreement.

Under the Torii Agreement, we will be responsible for supplying Torii with its required amounts of ORLADEYO for commercial sale. If due to the failure of our third-party contract manufacturers to produce sufficient drug product we fail to supply to Torii the required amounts of ORLADEYO, then Torii's ability to successfully commercialize ORLADEYO in Japan could be materially impaired, and we may receive less royalty income under the Torii Agreement, or none at all.

Any of the foregoing risks could materially adversely impact our ability to obtain regulatory approval of ORLADEYO in Japan, the price of ORLADEYO in Japan, and to perform our obligations under the Torii Agreement, which could materially reduce the economic benefits of the Torii Agreement to us and impair or result in the termination of our collaboration with Torii.

There can be no assurance that our commercialization efforts, methods, and strategies for our products or technologies will succeed, and our future revenue generation is uncertain.

There can be no assurance that our commercialization efforts, methods and strategies will succeed. Although we have expanded and added experienced professionals to our internal commercial team, as a company we do not have a great deal of experience in commercializing our product candidates or technologies. In addition, we may be unable to establish or sufficiently increase our sales, marketing and distribution capabilities for products we currently, or plan to, commercialize. Our ability to receive revenue from products we or our partners commercialize is subject to several risks, including:

- we or our partners may fail to successfully complete clinical trials, or satisfy post-marketing commitments, sufficient to obtain and keep regulatory agency marketing approval;
- many competitors are more experienced and have significantly more resources, and their products could reach the market faster, be more cost effective or have a better efficacy or tolerability profile than our product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy, which could result in decreased commercial value of our Company and our products;
- we may fail to employ a comprehensive and effective regulatory strategy, which could result in a delay or failure in commercialization of our products;
- our ability to successfully commercialize our products is affected by the competitive landscape, which cannot be fully known at this time;
- revenue from product sales would depend on our ability to obtain and maintain favorable pricing;
- reimbursement is constantly changing, which could greatly affect usage of our products;
- future revenue from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, and manufacture, market, distribute and commercialize our approved drugs; and
- the impact of the COVID-19 pandemic on us or our partners.

We expect to continue expanding our development and regulatory capabilities and implementing sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to continue experiencing significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates currently in development receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. For example, as we approach the commercial launch of ORLADEYO, we've expanded our internal commercial team. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. In addition, if a commercial launch for any product or product candidate for which we recruit a commercial team and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We depend on third-party vendors, including third-party manufacturers and distributors, to manufacture and distribute our products, product candidates and the materials for our product candidates. Often, especially early in the development and commercialization process, we have only one or limited sources for a particular product or service, such as manufacturing and/or distribution. If we cannot rely on existing third-party vendors, we will be required to incur significant costs and potential delays in finding new third-party vendors, which could adversely impact the development and commercialization timeframes for our products and product candidates.

We depend on these third-party vendors to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party vendors, particularly our third-party manufacturers and distributors, which may be the only vendor we have engaged for a particular product or service, may encounter difficulties with meeting our requirements, including but not limited to problems involving, as applicable:

- insufficient resources being devoted in the manner necessary to satisfy our requirements within expected timeframes;
- inconsistent production yields;
- product liability claims or recalls of commercial product;
- difficulties in scaling production to commercial and validation sizes;
- interruption of the delivery of materials required for the manufacturing process;
- failure to distribute commercial supplies of our products to commercial vendors or end users in a timely manner;
- scheduling of plant time with other vendors or unexpected equipment failure;
- potential catastrophes that could strike their facilities or have an effect on infrastructure;
- potential impurities in our drug substance or products that could affect availability of product for our clinical trials or future commercialization;
- poor quality control and assurance or inadequate process controls;
- failure to provide us with accurate or timely information regarding inventories, the number of patients who are using our products, or serious adverse events and/or product complaints regarding our products;
- inability of third parties to satisfy their financial obligations to us or to others;
- potential breach of the manufacturing or distribution agreement by the third party;
- possible termination or nonrenewal of a critical agreement by the third party at a time that is costly or inconvenient to us; and
- lack of compliance or cooperation with regulations and specifications or requests set forth by the FDA or other foreign regulatory agencies or local customs, particularly associated with ORLADEYO, BCX9930, BCX9250, galidesivir, peramivir and our early stage compounds.

Many additional factors could cause production or distribution interruptions with the manufacture and distribution of any of our products and product candidates, including human error, natural disasters, pandemics, labor disputes, acts of terrorism or war, equipment malfunctions, or raw material shortages.

In addition, our contract manufacturers may not be able to manufacture the materials required for our product candidates at a cost or in quantities necessary to make them commercially viable. Our raw materials, drug substances, and product candidates are manufactured by a limited group of suppliers, including some at a single facility. If any of these suppliers were unable to produce these items, this could significantly impact our supply of product candidate material for further preclinical testing and clinical trials. To date, our third-party manufacturers have met our manufacturing requirements, but they may not continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval in accordance with the FDA's cGMP and comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or foreign regulatory authorities may at any time implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties any of which could be costly to us and could result in a delay or shortage of product.

If we are unable to maintain current third-party relationships, or enter into new agreements with additional third parties on commercially reasonable terms, or if there is poor manufacturing or distribution performance or failure to comply with any regulatory agency on the part of any of our third-party vendors, we may not be able to complete development of, obtain timely approval of, or commercialize, our product candidates.

Commercialization of peramivir by our partners is subject to the potential commercialization risks described herein and numerous additional risks. Any potential revenue benefits to us in the form of milestone payments, royalties or other consideration are highly speculative.

Commercialization success of peramivir is uncertain and is subject to all the risks and uncertainties disclosed in our other risk factors relating to drug development and commercialization. In addition, commercialization of peramivir products is subject to further risks and may be negatively impacted by a number of factors, including, but not limited to, the following:

- peramivir may not prove to be adequately safe and effective for market approval in markets other than the United States, Canada, Japan, Korea, Taiwan, Australia and the European Union ("EU");
- necessary funding for post-marketing commitments and further development of peramivir may not be available timely, at all, or in sufficient amounts;
- flu prevention or pandemic treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines or other antivirals, including competitive i.v. antivirals, could substantially replace potential demand for peramivir;
- a limited number of governmental entities are expected to be the primary potential stockpiling customers for peramivir and if we are not successful at marketing peramivir to these entities for any reason, we will not receive substantial revenues from stockpiling orders;
- government and third-party payors may not provide sufficient coverage or reimbursement which would negatively impact the demand for peramivir;
- we may not be able to supply commercial material to our partners and our partners may not be able to maintain or establish sufficient and acceptable commercial manufacturing, either directly or through third-party manufacturers;
- the commercial demand and acceptance for peramivir by healthcare providers and by patients may not be sufficient to result in substantial revenues of peramivir to our partners and may result in little to no milestones or royalties to us;
- effectiveness of marketing and commercialization efforts for peramivir by our partners;
- market satisfaction with existing alternative therapies;
- perceived efficacy relative to other available therapies;
- disease prevalence;
- cost of treatment;
- pricing and availability of alternative products;

- marketing and sales activities of competitors;
- shifts in the medical community to new treatment paradigms or standards of care; and
- relative convenience and ease of administration.

Risks Relating to Competing in Our Industry

We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and substantial technological change. There are many companies seeking to develop products for the same indications that we currently target. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies and specialized biotechnology firms. Most of these competitors have greater resources than we do, including greater financial resources, larger research and development staffs and more experienced marketing and manufacturing organizations. In addition, most of our competitors have greater experience than we do in conducting clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals of product candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including patent and FDA exclusivity rights that would delay our ability to market products. We face, and will continue to face, competition in the licensing of potential product candidates for desirable disease targets, licensing of desirable product candidates, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. This includes competition with respect to, among other things, galidesivir as a potential treatment for COVID-19. Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We are performing research on or developing products for the treatment of several rare diseases, including HAE, diseases of the complement system, and FOP, as well as developing broad spectrum antivirals for use as medical countermeasures. We expect to encounter significant competition for any of the pharmaceutical products we are developing and plan to develop. Companies that complete clinical trials, obtain required funding or government support, obtain required regulatory approvals and commence commercial sales or stockpiling orders of their products before their competitors may achieve a significant competitive advantage. There are licensed therapies for HAE (including Berinert®, Haegarda®, Cinryze®, Kalbitor®, Takhzyro®, Firazyr® (icatibant), generic icatibant, and Ruconest®), therapies for certain complement-mediated diseases such as PNH, aHUS, myasthenia gravis, and neuromyelitis optica spectrum disorder (Soliris® and Ultomiris™), products for the prevention or treatment of influenza (seasonal flu vaccines, Tamiflu® (oseltamivir), generic oseltamivir, Relenza®, and Inavir®, favipiravir, and Xofluza™), remdesivir as a potential treatment for COVID-19 and a number of additional products in clinical development in these therapeutic areas and for the treatment of FOP. In addition, various government entities throughout the world may offer incentives, grants and contracts to encourage additional investment into preventative and therapeutic agents against viruses such as influenza, coronavirus, Ebola, and others, which may have the effect of further increasing the number of our competitors and/or providing advantages to certain competitors. See “Item 1. Business—Competition” in our Annual Report on Form 10-K for the year ended December 31, 2019 for further discussion of our competitors, competitive products or programs, and the competitive conditions in these and other therapeutic areas.

If one or more of our competitors’ products or programs, including potential competitors not currently identified, are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and

- production facilities.

Any of these competitive factors could impede our funding efforts, render technology and product candidates noncompetitive or eliminate or reduce demand for our product candidates.

Legal and Regulatory Risks

We are subject to various laws and regulations related to our products and product candidates and, if we or our partners do not comply with these laws and regulations, we could face substantial penalties.

Our or our partners’ activities related to approved products, such as RAPIVAB/ALPIVAB (peramivir), or, following their regulatory approval, any of our product candidates under development, such as ORLADEYO, BCX9930, BCX9250, and galidesivir, are subject to regulatory and law enforcement authorities in the United States (including the FDA, the Federal Trade Commission, the Department of Justice, and state and local governments) and their foreign equivalents (including the EMA, MHLW, MHRA, and others).

We are responsible for reporting adverse drug experiences, have responsibility for certain post-approval studies, and may have responsibilities and costs related to a recall or withdrawal of RAPIVAB/ALPIVAB from sale in the jurisdictions in which it is approved. We may also incur liability associated with RAPIVAB/ALPIVAB manufacturing contracted by us or in support of any of our partners. We are required to maintain records and provide data and reports to regulatory agencies related to RAPIVAB/ALPIVAB (e.g. risk evaluation and mitigation strategies, track and trace requirements, adverse events), and we may incur certain promotional regulatory and government pricing risks, all of which could have a material adverse impact on our operations and financial condition. Similar responsibilities would apply upon regulatory approval of any of our other product candidates currently under development.

In addition, we are subject to the federal physician sunshine act and certain similar physician payment and drug pricing transparency legislation in various states. We are also subject to various federal and state laws pertaining to health care “fraud and abuse,” including both federal and state anti-kickback and false claims laws. Outside of the United States, we may be subject to analogous foreign laws and regulations in the various jurisdictions in which we operate. These laws and regulations apply to our or our partners’ operations, sales and marketing practices, price reporting, and relationships with physicians and other customers and third-party payors. Anti-kickback laws generally prohibit a manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for reimbursement or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The sunshine provisions apply to manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government certain payments made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as, ownership and investment interests held by physicians (as defined above) and their immediate family members. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Although we seek to comply with these statutes, it is possible that our practices, or those of our partners, might be challenged under health care fraud and abuse, anti-kickback, false claims or similar laws. Violations of the physician sunshine act and similar legislation or the fraud and abuse laws may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

The principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to certain regulatory authorities, including the FDA and comparable foreign regulatory authorities. Consequently, the FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator creates a conflict of interest or otherwise affects interpretation of the study. In the event of a conflict of interest with respect to a study, the integrity of the data generated at the applicable clinical trial site may be questioned or the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

We have a number of outstanding post-approval commitments to the FDA and EMA that we retain, which we may not complete successfully or on time for any number of reasons, including but not limited to lack of funds to complete the studies and insufficient interest by appropriate sites, investigators or study subjects. For example, as a condition of the approval of RAPIVAB/ALPIVAB, we were required to complete pediatric patient trials and to submit the final results of these clinical trials to the FDA and EMA. We may be subject to penalties if we fail to comply with post-approval legal and regulatory requirements and our products could be subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to the other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, the approval of RAPIVAB/ALPIVAB and any other future product candidates may be subject to requirements for costly post-approval testing and surveillance to monitor its safety or efficacy.

Advertising and promotion are subject to stringent FDA rules and oversight, and as an NDA-holder, we may be held responsible for any advertising and promotion that is not in compliance with the rules and regulations. In particular, the claims in all promotional materials and activities must be consistent with the FDA approvals for approved products and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of the products. We are also required to engage in appropriate truthful, non-misleading, and non-promotional scientific exchange concerning our products, and applicable regulatory authorities, competitors, and other third parties may take the position that we are not in compliance with such regulations. In addition to medical education efforts, we may offer patient support services to assist patients receiving treatment with our commercially approved products which have increasingly become the focus of government investigation.

Adverse event information concerning approved products must be reviewed, and as an NDA-holder, we are required to make expedited and periodic adverse event reports to the FDA and other regulatory authorities. In addition, the research, manufacturing, distribution, sale and promotion of products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, state and local governments, and foreign equivalents of the foregoing. All of these activities are also potentially subject to healthcare false claims and fraud and abuse laws, as well as consumer protection and unfair competition laws.

If our operations with respect to RAPIVAB/ALPIVAB or our other products that are subject to healthcare laws and regulations are found to be in violation of any of the healthcare fraud and abuse laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with all applicable fraud and abuse laws may be costly.

Our employees and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are subject to the risk of fraud or other misconduct by our employees and consultants, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee and consultant misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee and consultant misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We and our partners may be subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance and adversely affect our or our partners' ability to market our products, obtain collaborators and raise capital.

The Patient Protection and Affordable Care Act, or PPACA, made extensive changes to the delivery of health care in the U.S. The PPACA included numerous provisions that affect pharmaceutical companies, some of which became effective immediately and others of which have taken effect over the past several years. For example, the PPACA expanded health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposed substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA also contains cost containment measures that could reduce reimbursement levels for health care items and services generally, including pharmaceuticals. It also required reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals.

We expect that the current presidential administration and U.S. Congress may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the PPACA or undertake other reforms that impact the pharmaceutical industry. For instance, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications within the established Prescription Drug User Fee Act time frames, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. There is still significant uncertainty with respect to the impact that the current presidential administration and the U.S. Congress may have on the PPACA specifically and the healthcare industry generally, and any changes will likely take time to unfold. As such, we cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. In addition, pharmaceutical and device manufacturers are also required to report and disclose certain payments and transfers of value to, and investment interests held by, physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. Compliance with the PPACA and state laws with similar provisions is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, legislation has been enacted in certain states and at a federal level that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. Compliance with these electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. In addition, our compliance may be deemed insufficient and we could face a material adverse effect on our business, financial condition, results of operations and growth prospects. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Adequate coverage and reimbursement in the U.S. and other markets is critical to the commercial success of RAPIVAB or any other product that we might bring to market, including ORLADEYO. Recently in the U.S. there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. Third-party payors are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many third-party payors negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the third-party payor's patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take several months before a particular payor initially reviews our product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of RAPIVAB or any other product we might bring to market, including ORLADEYO. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all which may have a material adverse effect on our business, financial condition and results of operations.

We are subject to data security and privacy risks, and our actual or perceived failure to comply with regulations and other legal obligations related to privacy and data protection could harm our business.

We are subject to legal obligations related to privacy and data protection. Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use, and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. For example, we are subject to the California Consumer Privacy Act, which gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. We are also subject to the General Data Protection Regulation in the EU. See "Risk Factors—Risks Relating to Our Business—Risks Relating to International Operations—Our actual or perceived failure to comply with European governmental regulations and other legal obligations related to privacy, data protection and information security could harm our business" for additional discussion of international privacy laws and regulations. Failure to comply with these laws and regulations could result in government enforcement actions, private litigation, or harm to our reputation and our business.

If because of our use of hazardous materials, we violate any environmental controls or regulations that apply to such materials, we may incur substantial costs and expenses in our remediation efforts.

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result, and any liabilities could exceed our resources. Compliance with environmental laws and regulations or a violation of such environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

Intellectual Property Risks

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of those rights would diminish.

Our success will depend in part on our ability and the abilities of our partners to obtain, protect and enforce viable intellectual property rights including but not limited to trade name, trademark and patent protection for our Company and its products, methods, processes and other technologies we may license or develop, to preserve our trade secrets, and to operate without infringing the proprietary rights of third parties both domestically and abroad. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the United States Patent and Trademark Office ("USPTO"), the Patent Cooperation Treaty offices, nor the courts of the United States and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. Further, we may not have worldwide patent protection for all of our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. In some jurisdictions, some of our product candidates in certain programs, including our HAE program, may have short or no composition of matter patent life and we may therefore rely on orphan drug exclusivity or data exclusivity. There can be no assurance that we will obtain orphan drug exclusivity or data exclusivity in every jurisdiction. Further, in some jurisdictions, we may rely on formulation patents or method of use patents. Both the ability to achieve issuance and the enforcement of formulation and method of use patents can be highly uncertain and can vary from jurisdiction to jurisdiction, and such patents may therefore not adequately prevent competitors and potential infringers in some jurisdictions. The validity, scope, enforceability and commercial value of the rights protected by such patents, therefore, is highly uncertain.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and unsuccessful. An adverse result in any legal proceeding could put one or more of our patents at risk. Our success depends in part on avoiding the infringement of other parties' patents and other intellectual property rights as well as avoiding the breach of any licenses relating to our technologies and products. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, avoiding patent infringement may be difficult and we may inadvertently infringe third-party patents or proprietary rights. These third parties could bring claims against us, our partners or our licensors that even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, our partners or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our partners or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

If we or our partners are unable or fail to adequately initiate, protect, defend or enforce our intellectual property rights in any area of commercial interest or in any part of the world where we wish to seek regulatory approval for our products, methods, processes and other technologies, the value of the product candidates to produce revenue would diminish. Additionally, if our products, methods, processes, and other technologies or our commercial use of such products, processes, and other technologies, including but not limited to any trade name, trademark or commercial strategy infringe the proprietary rights of other parties, we could incur substantial costs. The USPTO and the patent offices of other jurisdictions have issued to us a number of patents for our various inventions and we have in-licensed several patents from various institutions. We have filed additional patent applications and provisional patent applications with the USPTO. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate. We have also filed certain trademark and trade name applications worldwide. We cannot assure you as to:

- the degree and range of protection any patents will afford against competitors with similar products;

- if and when patents will issue;
- if patents do issue, we cannot be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the USPTO or other foreign patent office upholds patents issued to others or if the USPTO grants patent applications filed by others, we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in those patents; or
- pay damages.

We may initiate, or others may bring against us, litigation or administrative proceedings related to intellectual property rights, including proceedings before the USPTO or other foreign patent office. Any judgment adverse to us in any litigation or other proceeding arising in connection with a patent or patent application could materially and adversely affect our business, financial condition and results of operations. In addition, the costs of any such proceeding may be substantial whether or not we are successful.

Our success is also dependent upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license or commercialize our product candidates and any such events would significantly impair the value of such product candidates.

Product Liability Risks

We face an inherent risk of liability in the event that the use or misuse of our products results in personal injury or death and our product liability insurance coverage may be insufficient.

If the use or misuse of peramivir, forodesine or any other regulatory body-approved products we or a partner may sell in the future harms people, we may be subject to costly and damaging product liability claims brought against us by consumers, healthcare providers, pharmaceutical companies, third-party payors or others. The use of our product candidates in clinical trials, including post marketing clinical studies, could also expose us to product liability claims. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates and, therefore, the amount of insurance coverage we currently have may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could give rise to a substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our clinical trials. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;
- withdrawal of clinical trial volunteers or patients;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- the diversion of management's attention from managing our business.

Risks Relating to Our Contractual Arrangements

We face risks related to our government-funded programs; if BARDA/HHS or NIAID/HHS were to eliminate, reduce or delay funding from our contracts, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows.

We have completed work under a contract with BARDA/HHS for the development of RAPIVAB and have entered into contracts with BARDA/HHS and NIAID/HHS for the development of galidesivir as a treatment for diseases caused by RNA pathogens, including COVID-19, Marburg virus disease, Yellow Fever and Ebola virus disease. In contracting with these government agencies, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or, if we are found to be in violation, could result in contract termination. If the U.S. Government terminates any of its contracts with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

U.S. Government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on U.S. Government contracts. These risks include the ability of the U.S. Government to unilaterally:

- terminate or reduce the scope of our contract with or without cause;
- interpret relevant regulations (federal acquisition regulation clauses);
- require performance under circumstances which may not be favorable to us;
- require an in-process review where the U.S. Government will review the project and its options under the contract;
- control the timing and amount of funding, which impacts the development progress of our programs; and
- audit and object to our contract-related costs and fees, including allocated indirect costs.

The U.S. Government may terminate its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination does not permit these recoveries under default provisions. In the event of termination or upon expiration of a contract, the U.S. Government may dispute wind-down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. Government for denying certain payments under a contract, such a challenge could subject us to substantial additional expenses which we may or may not recover. Further, if the U.S. Government terminates its contracts with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

As a U.S. Government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. Government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Audits under the active BARDA/HHS and NIAID/HHS galidesivir contracts may occur at the election of the U.S. Government and have been concluded through fiscal 2015; all subsequent fiscal years are still open and auditable. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contracts prospectively. In addition, in the event BARDA/HHS or NIAID/HHS determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, BARDA/HHS or NIAID/HHS would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. Government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. Government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. Government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

There are risks related to the potential government use or sale of our antivirals.

Government use or sale, in emergency situations or otherwise, of our antivirals—including peramivir for the treatment of influenza or galidesivir as a potential treatment for COVID-19—may result in risks to us or our collaborative partners. There can be no assurance that government use of our antivirals (whether as indicated or outside of their current indications) will prove to be generally safe, well-tolerated and effective. Any government sale or use (on an emergency basis or otherwise) of our antivirals in any country may create liabilities for us or our partners.

We have entered into a contract with the CDC for the procurement of up to 50,000 doses of RAPIVAB (peramivir injection) over a five-year period. In addition, we are conducting a randomized, double-blind, placebo-controlled clinical trial to assess the safety, clinical impact and antiviral effects of galidesivir in patients with COVID-19. The trial is being funded by NIAID/HHS. We have ongoing studies with NIAID/HHS and academic collaborators to assess the activity of galidesivir against SARS-CoV-2, the virus that causes COVID-19, in both in vitro and animal models. We are also working with NIAID/HHS to increase manufacturing yield and expand the current supply of the drug. There can be no assurance that we or our manufacturers will be able to fully meet the demand for such antivirals with respect to these or future arrangements. Further, we may not receive a favorable purchase price for future orders of our antivirals by governmental entities. Our competitors may develop products that could compete with or replace any antivirals selected for government sale or use. We may face competition in markets where we have no existing intellectual property protection or are unable to successfully enforce our intellectual property rights.

There can be no assurance that the non-U.S. partnerships that we have entered into for peramivir will result in any order for peramivir in those countries or that peramivir will be approved for any use or will achieve market approval in additional countries. There can be no assurance that galidesivir will be approved for use in any countries. In the event that any emergency use or market approval is granted in any country, there can be no assurance that any government order or commercialization of the applicable product or product candidate in such countries will be substantial or will be profitable to us.

If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and seek additional remedies.

If we are unable or fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, product supply obligations, post approval commitments, or development and commercial diligence obligations; are unable or fail to make milestone payments or material data use payments in accordance with applicable provisions; or fail to pay the minimum annual payments under any of our in-licenses relating to our products or product candidates, our licensors may terminate the applicable license or seek other available remedies. As a result, our development of the respective product candidate or commercialization of the product would cease.

Royalties and milestone payments from Shionogi under our license agreement with Shionogi (the "Shionogi Agreement") are required to be used by Royalty Sub to service its obligations under its PhaRMA Notes, and generally will not be available to us for other purposes unless and until Royalty Sub has repaid in full its obligations under the PhaRMA Notes.

In March 2011, our wholly-owned subsidiary, Royalty Sub, issued $30.0 million in aggregate principal amount of PhaRMA Notes. The PhaRMA Notes are secured principally by (i) certain royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from us the rights to market peramivir in Japan and Taiwan, (ii) rights to certain payments under a Japanese yen/U.S. dollar Currency Hedge Agreement put into place by us in connection with the issuance of the PhaRMA Notes and (iii) the pledge by us of our equity interest in Royalty Sub. Payments from Shionogi to us on non-governmental sales under the Shionogi Agreement will generally not be available to us for other purposes unless and until Royalty Sub has repaid in full its obligations under the PhaRMA Notes. Accordingly, these funds have been and will continue to be required to be dedicated to Royalty Sub's debt service and not available to us for product development or other purposes. Since September 1, 2014, payments from Shionogi have been insufficient for Royalty Sub to service its obligations under the PhaRMA Notes, resulting in a continuing event of default with respect to the PhaRMA Notes since that time. As a result of the continuing event of default, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs and we might otherwise be adversely affected.

The PhaRMA Notes have a final legal maturity date of December 1, 2020, at which time the outstanding principal amount of the PhaRMA Notes, together with accrued and unpaid interest, will be due in full. The failure by Royalty Sub to repay in full the outstanding principal amount of the PhaRMA Notes, together with any accrued and unpaid interest, at the December 1, 2020 final maturity date would constitute an additional event of default under the PhaRMA Notes. We do not currently expect that Royalty Sub will be able to repay the PhaRMA Notes at final maturity. We cannot predict whether holders of PhaRMA Notes will seek to pursue any remedies as a result of the continuing event of default with respect to the PhaRMA Notes or at final maturity if Royalty Sub fails to pay the PhaRMA Notes in full at final maturity. The PhaRMA Notes are the obligation of Royalty Sub. As a result, we do not currently expect the continuing event of default on the PhaRMA Notes, or a failure by Royalty Sub to repay the PhaRMA Notes at final maturity, to have a significant impact on our future results of operations or cash flows. However, we cannot assure you that this will be the case or that we will not otherwise be adversely affected as a result the continuing event of default under the PhaRMA Notes or a failure by Royalty Sub to repay the PhaRMA Notes at maturity.

Because a continuing event of default exists under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub. In addition, we do not currently expect that Royalty Sub will be able to repay the PhaRMA Notes at final maturity on December 1, 2020. As a result, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes and we could otherwise be adversely affected.

As Royalty Sub has been unable to service its obligations under the PhaRMA Notes and a continuing event of default exists under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs and we might otherwise be adversely affected. In addition, the PhaRMA Notes have a final legal maturity date of December 1, 2020, at which time the outstanding principal amount of the PhaRMA Notes, together with accrued and unpaid interest, will be due in full. The failure by Royalty Sub to repay in full the outstanding principal amount of the PhaRMA Notes, together with any accrued and unpaid interest, at the December 1, 2020 final maturity date would constitute an additional event of default under the PhaRMA Notes. We do not currently expect that Royalty Sub will be able to repay the PhaRMA Notes at final maturity. We cannot predict whether holders of PhaRMA Notes will seek to pursue any remedies as a result of the continuing event of default with respect to the PhaRMA Notes or at final maturity if Royalty Sub fails to pay the PhaRMA Notes in full at final maturity. The PhaRMA Notes are the obligation of Royalty Sub. As a result, we do not currently expect the continuing event of default on the PhaRMA Notes, or a failure by Royalty Sub to repay the PhaRMA Notes at final maturity, to have a significant impact on our future results of operations or cash flows. However, we cannot assure you that this will be the case or that we will not otherwise be adversely affected as a result the continuing event of default under the PhaRMA Notes or a failure by Royalty Sub to repay the PhaRMA Notes at maturity.

Our Second Amended and Restated Senior Credit Facility contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a material adverse effect on our business.

The Second Amended and Restated Senior Credit Facility contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease, license, transfer or otherwise dispose of certain parts of our business or property;
- change the nature of our business;
- liquidate or dissolve;
- enter into certain change in control or acquisition transactions;
- incur or assume certain debt, including accessing additional tranches of debt under the Second Amended and Restated Senior Credit Facility;
- grant certain types of liens on our assets;
- modify, liquidate or transfer assets in certain collateral accounts;
- pay dividends or make certain distributions to our stockholders;
- make certain investments;
- enter into material transactions with affiliates; and
- modify existing debt or collaboration arrangements.

The restrictive covenants contained in the Second Amended and Restated Senior Credit Facility could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial without the lender's permission or without repaying all Second Amended and Restated Senior Credit Facility obligations.

A breach of any of these covenants could result in an event of default under the Second Amended and Restated Senior Credit Facility. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Second Amended and Restated Senior Credit Facility occurs. In the case of a continuing event of default under the agreement, the lender could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted to the lender a security interest under the Second Amended and Restated Senior Credit Facility, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Second Amended and Restated Senior Credit Facility are secured by substantially all of our assets and those of our subsidiaries, excluding certain specified assets but including proceeds from those assets.

Risks Relating to International Operations

International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks.

Our business strategy includes international expansion, including the commercialization of products outside of the United States. We currently conduct clinical studies and regulatory activities and have hired, and expect to continue hiring, employees outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy and data regulations, transparency regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- introduction of new health authority requirements and/or changes in health authority expectations;
- failure by us or our partners to obtain and maintain regulatory approvals for the use of our products in various countries;

- complexities and difficulties in obtaining protection for, and enforcing, our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits on our ability to penetrate international markets;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;

- natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, actual or threatened public health emergencies and outbreak of disease (including for example, the recent coronavirus outbreak), boycotts, adoption or expansion of government trade restrictions, and other business restrictions;

- certain expenses including, among others, expenses for travel, translation, and insurance;

- regulatory and compliance risks that relate to maintaining accurate information and control over commercial operations and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, including its books and records provisions or anti-bribery provisions, or the U.K. Bribery Act and similar foreign laws and regulations; and

- regulatory and compliance risks relating to doing business with any entity that is subject to sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury.

Any of these factors could significantly harm our future international expansion of operations and, consequently, our business and results of operations.

Additionally, in some countries, such as Japan and the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Our actual or perceived failure to comply with European governmental regulations and other legal obligations related to privacy, data protection and information security could harm our business.

EU member states, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation ("GDPR") imposes strict requirements on controllers and processors of personal data, including special protections for "special category data," which includes health, biometric and genetic information of data subjects located in the EU. Further, GDPR provides a broad right for EU member states to create supplemental national laws, for example relating to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase and harm our business and financial condition. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the EU to the United States or other regions that have not been deemed to offer "adequate" privacy protections.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states, which may deviate slightly from the GDPR, may result in significant fines of up to 4% of global revenues, or €20.0 million, whichever is greater, and in addition to such fines, our failure to comply with the requirements of GDPR may subject us to litigation and/or adverse publicity, which could have material adverse effects on our reputation and business. As a result of the implementation of the GDPR, we are required to put in place additional mechanisms to ensure compliance with the new data protection rules. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU, imposes additional obligations on us when we are contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit.

We are subject to the supervision of local data protection authorities in those jurisdictions where we undertake clinical trials. We depend on a number of third parties in relation to the provision of our services, a number of which process personal data of EU individuals on our behalf. With each such provider we are required to enter into contractual arrangements under which they are contractually obligated to only process personal data according to our instructions, and conduct diligence to ensure that they have sufficient technical and organizational security measures in place.

We are also subject to evolving European privacy laws on electronic marketing and cookies. The EU is in the process of replacing the e-Privacy Directive (2002/58/EC) with a new set of rules taking the form of a regulation that will be directly implemented in the laws of each European member state. While this e-Privacy Regulation was originally intended to be adopted on May 25, 2018, it is still going through the European legislative process and the timing of its adoption remains unclear.

The United Kingdom's decision to withdraw from the EU could result in increased regulatory and legal complexity, which may make it more difficult for us to do business in Europe and impose additional challenges in securing regulatory approval of our product candidates in Europe.

The United Kingdom's exit from the EU, or Brexit, has caused political and economic uncertainty, including in the regulatory framework applicable to our operations and product candidates, and this uncertainty may persist for years. Brexit could, among other outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. For instance, preparations for Brexit have resulted in the decision to move the EMA from the United Kingdom to the Netherlands. This transition may cause disruption or delays in granting clinical trial authorization or opinions for marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations.

The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the United Kingdom. It is possible that there will be increased regulatory complexities, which can disrupt the timing of our clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenues and achieve and sustain profitability.

In addition, as a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the EU. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the EU would have and how such withdrawal would affect us, and the full extent to which our business could be adversely affected.

Risks Relating to Technology

If our facility incurs damage or power is lost for a significant length of time, our business will suffer.

We store clinical and stability samples at our facility that could be damaged if our facility incurs physical damage or in the event of an extended power failure. We have backup power systems in addition to backup generators to maintain power to all critical functions, but any loss of these samples could result in significant delays in our drug development process.

In addition, we store most of our preclinical and clinical data at our facilities. Duplicate copies of most critical data are secured off-site. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

A significant disruption in our information technology systems or a cyber-security breach could adversely affect our business.

We are increasingly dependent on information technology systems to operate our business. In addition, the FDA and comparable foreign regulatory authorities regulate, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facility incurs damage, or if our vendor data systems fail, suffer damage or are destroyed.

Like other companies in our industry, our networks and infrastructure may be vulnerable to cyber-attacks or intrusions, including by computer hackers, foreign governments, foreign companies or competitors, or may be breached by employee error, malfeasance or other disruption. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems could negatively impact operations. If our systems are damaged, fail to function properly or otherwise become unavailable, we may incur substantial costs to repair or replace them, and we may experience loss of critical data and interruptions or delays in our ability to perform critical functions, which could adversely affect our business, financial condition or results of operations. Any compromise of our data security could also result in a violation of applicable privacy and other laws, significant legal and financial exposure, damage to our reputation, loss or misuse of the information and a loss of confidence in our data security measures, which could harm our business. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems, or those of third parties with which we do business, and any such events could adversely affect our business.

Risks Relating to Investing in Our Common Stock

Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.

Several of our stockholders own greater than 5% of our outstanding common stock. Our top ten stockholders own more than 50% of BioCryst and can individually, and as a group, influence our operations based upon their concentrated ownership. These stockholders, if they act together, may be able to influence the outcome of matters requiring approval of the stockholders, including the election of our directors and other corporate actions.

Our stock price has been, and is likely to continue to be, highly volatile, which could cause the value of an investment in our common stock to decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended September 30, 2020, the 52-week range of the market price of our stock was from $1.38 to $6.29 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;

- developments or disputes concerning patents or proprietary rights;

- additional dilution through sales of our common stock or other derivative securities;

- status of new or existing licensing or collaborative agreements and government contracts;

- announcements relating to the status of our programs;
- developments and announcements regarding new and virulent strains of influenza;
- we or our partners achieving or failing to achieve development milestones;
- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- publicity regarding certain public health concerns for which we are or may be developing treatments;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of pharmaceutical products;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel or members of our board of directors;
- purchases or sales of substantial amounts of our stock by existing stockholders, including officers or directors;
- economic and other external factors or other disasters or crises; and
- period-to-period fluctuations in our financial results.

Future sales and issuances of securities may dilute the ownership interests of our current stockholders and cause our stock price to decline.

Future sales of our common stock by current stockholders into the public market could cause the market price of our stock to fall. As of October 31, 2020, there were 176,565,622 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition. We may also sell, for our own account, shares of common stock or other equity securities, from time to time at prices and on terms to be determined at the time of sale.

As of October 31, 2020, there were 18,362,390 stock options outstanding and 11,433,039 shares available for issuance under our Amended and Restated Stock Incentive Plan, 3,671,668 stock options outstanding and 728,332 shares available for issuance under our Inducement Equity Incentive Plan and 2,872,764 shares available for issuance under our Amended and Restated Employee Stock Purchase Plan. In addition, we could also make equity grants outside of our Amended and Restated Stock Incentive Plan or Amended and Restated Inducement Equity Incentive Plan. The shares underlying existing stock options, restricted stock units and possible future stock options, stock appreciation rights and stock awards have been registered pursuant to registration statements on Form S-8.

If some or all of such shares are sold or otherwise issued into the public market over a short period of time, our current stockholders' ownership interests may be diluted and the value of all publicly traded shares is likely to decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales and issuances may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

In March 2017, we entered into a Registration Rights Agreement with entities affiliated with Baker Bros. Advisors LP (the "Baker Entities") to provide that, if requested, we will register the shares of our common stock beneficially owned by the Baker Entities for resale under the Securities Act. Our registration obligations pursuant to the Registration Rights Agreement cover all shares then held or thereafter acquired by the Baker Entities, for up to ten years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. On May 10, 2017, we filed a registration statement on Form S-3 with respect to 11,710,951 shares of common stock held by the Baker Entities. Subsequently, on November 21, 2019, certain of the Baker Entities acquired pre-funded warrants to purchase 11,764,706 shares of our common stock at a price of $1.69 per warrant. In addition, on June 1, 2020, we issued pre-funded warrants to purchase 3,511,111 shares of our common stock at a price of $4.49 per warrant, including pre-funded warrants acquired by certain of the Baker Entities to purchase 3,252,375 shares of our common stock. Each warrant has an exercise price of $0.01 per share. If the Baker Entities, by exercising their underwriting rights or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities intend to sell a large number of our shares, this could adversely affect the market price of our common stock.

We have anti-takeover provisions in our corporate charter documents that may result in outcomes with which you do not agree.

Our board of directors has the authority to issue up to 5,000,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our certificate of incorporation provides for staggered terms for the members of the board of directors and supermajority approval of the removal of any member of the board of directors and prevents our stockholders from acting by written consent. Our certificate also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our by-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future.

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

Our Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which may limit a stockholder's ability to obtain a favorable judicial forum for such disputes with us or our directors, officers or employees.

Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, stockholders, employees or agents to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents arising out of or relating to any provision of the General Corporation Law of Delaware or our Certificate of Incorporation or Amended and Restated Bylaws or (iv) any action against us or any of our directors, officers, stockholders, employees or agents governed by the internal affairs doctrine of the State of Delaware. This exclusive forum provision does not apply to establish the Delaware Court of Chancery as the forum for actions or proceedings brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

This exclusive forum provision may limit a stockholder's ability to choose its preferred judicial forum for disputes with us or our directors, officers, employees or agents, which may discourage the filing of lawsuits with respect to such claims. If a court were to find this exclusive forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in another jurisdiction, which could adversely affect our business and financial condition.

General Risk Factors

Natural disasters, epidemic or pandemic disease outbreaks, trade wars, political unrest or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators or other third parties with whom we conduct business now or in the future.

A wide variety of events beyond our control, including natural disasters, epidemic or pandemic disease outbreaks (such as the ongoing COVID-19 pandemic), trade wars, political unrest or other events could disrupt our business or operations or those of our development partners (such as Torii), manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. If our operations or those of third parties with whom we have business are impaired or curtailed as a result of these events, the development and commercialization of our products and product candidates could be impaired or halted, which could have a material adverse impact on our business. See "Risk Factors—Risks Relating to Our Business—Our business, operations, clinical development or commercialization plans and timelines, and access to capital could be adversely affected by the effects of the recent COVID-19 pandemic on us or on third parties with whom we conduct business, including without limitation our development partners, manufacturers, CROs, and others, as well as on the regulatory and government agencies with whom we work."

We are subject to legal proceedings, which could result in losses or unexpected expenditure of time and resources.

From time to time, we may be involved in disputes, called upon to initiate legal proceedings or to defend ourselves in such legal proceedings relating to our business. Due to the inherent uncertainties in legal proceedings, we cannot accurately predict the ultimate outcome of any such proceedings. An unfavorable outcome in any such proceedings could have an adverse impact on our business, financial condition and results of operations. If our stock price is volatile, we may become involved in securities class action lawsuits in the future. Any current or future dispute resolution or legal proceeding, regardless of the merits of any such proceeding, could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business.

Insurance coverage is increasingly more costly and difficult to obtain or maintain.

While we currently have insurance for our business, property, directors and officers, and our products, insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to bear any loss in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our

insurance coverage, we may incur significant uninsured costs associated with loss or damage that could have an adverse effect on our operations and financial position. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all.

If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our product candidates and commercialization of our products and the related expansion of our business will be delayed or stopped.

We are highly dependent upon our senior management and scientific team, the unexpected loss of whose services might impede the achievement of our development and commercial objectives. This risk has been heightened in the current environment as a result of the ongoing COVID-19 pandemic. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, commercial, operational and scientific personnel will harm our business because we rely upon these personnel for many critical functions of our business.

Item 6. Exhibits

Number	Description
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed November 4, 2008.
3.4	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed May 7, 2014.
3.5	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed May 7, 2014.
3.6	Certificate of Elimination of the Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed May 13, 2020.
3.7	Certificate of Amendment to the Third Restated Certificate of Incorporation. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed May 13, 2020.
3.8	Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed November 4, 2008.
3.9	Amendment to Amended and Restated By-Laws of BioCryst Pharmaceuticals, Inc., dated January 21, 2018. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed January 22, 2018.
10.1	BioCryst Pharmaceuticals, Inc. Inducement Equity Incentive Plan (as amended and restated July 17, 2020). Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 (File No. 333-245024) filed August 12, 2020.
(10.2)	Amendment #23 to the Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases, dated August 21, 2020.
(10.3)	Amendment #23 to the Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases, dated September 14, 2020.
(10.4)*	Agreement, dated September 1, 2020, between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases.
(10.5)*	Amendment #1 to the Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases, dated October 14, 2020.
10.6	Amendment, dated August 31, 2020, to the Contract dated September 1, 2018 between BioCryst Pharmaceuticals, Inc. and the Department of Health and Human Services. Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed September 3, 2020.
(10.7)*	Third Amendment to Second Amended and Restated Credit and Security Agreement dated as of September 28, 2020, by and among Midcap Financial Trust, as administrative agent, the Lenders on the Credit Facility Schedule attached thereto and otherwise party thereto from time to time, BioCryst Pharmaceuticals, Inc., and MDCP, LLC.
(10.8)	Amendment #13 to the Agreement between BioCryst Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness Response, dated September 29, 2020.
(31.1)	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(31.2)	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32.1)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(32.2)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(101)	Financial statements from the Quarterly Report on Form 10-Q of BioCryst Pharmaceuticals, Inc. for the three and nine months ended September 30, 2020, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
(104)	Cover Page Interactive Data File – The cover page from this Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 is formatted in Inline XBRL (contained in Exhibit 101).
( )	Filed or furnished herewith.
*	Certain identified information has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the Company if publicly disclosed.

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 on this 6th day of November, 2020.

BIOCRYST PHARMACEUTICALS, INC.

/s/ Jon P. Stonehouse
Jon P. Stonehouse
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Anthony Doyle
Anthony Doyle
Senior Vice President, Chief Financial Officer
(Principal Financial Officer)

/s/ Michael L. Jones
Michael L. Jones
Executive Director, Finance and Principal Accounting Officer
(Principal Accounting Officer)

OMB Approval 2700-0042

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
	1		2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
Twenty-three (23)	August 15, 2020	5779392	

6. ISSUED BY — CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Office of Acquisitions
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY *(If other than Item 6)* — CODE N/A

MID RCB-A

8. NAME AND ADDRESS OF CONTRACTOR *(No. Street, county, State and ZIP: Code)*

BIOCRYST PHARMACEUTICALS, INC.
4505 EMPEROR BLVD SUITE 200
DURHAM, NC 27703

CODE | FACILITY CODE

(□) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

(X) 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSN272201300017C

10B. DATED *(SEE ITEM 13)* September 16, 2013

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

SOC 25.55 20-8470038 $2,896,627

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER Specify type of modification and authority) FAR 52.217-7, Mutual Agreement of the Parties

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return __ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

PURPOSE: The drug galidesivir was used in patients expressing COVID19 symptoms in the Yellow Fever Study in Brazil. The protocols have been amended to acknowledge the inclusion against Sars Cov2 virus. This equitable adjustment was mutually agreed to pay for additional costs associated with the human clinical trial and complete Phase I clinical studies for safety evaluation while optimizing dosing regimens.

The completion date of the contract is unchanged to September 30, 2022.
Total cost obligated by this action is changed from $43,034,602 to $45,931,229
Contract cost ceiling is changed to $45,931,229

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Jon P. Stonehouse CEO	John Outen, Contracting Officer Office of Acquisitions, DEA, NIAID, NIH, DHHS

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)	8/21/2020	BY John E. Outen -S Digitally signed by John E. Outen -S Date: 2020.08.21 10:37:05 -04'00' *(Signature of Contracting Officer)*	

Beginning with the effective date of this modification, ARTICLE B.2. ESTIMATED COST –OPTION AND ARTICLE G.3 INVOICE SUBMISSION /CONTRACT FINANCING REQUEST IS REVISED

ARTICLE B.2. ESTIMATED COST – Contract is revised to incorporate changes (a, and b) with changes in the table below:

a. The estimated cost of this contract is $45,931,229 with this revision with additional funds added.

b. Payments from the additional funds may be made from the following PRISM/NBS Line Item Numbers as follows:

PRISM/NBS Line Item No.	Description	PRISM/NBS Line Item Period of Performance	Funded Amount
21	Mad Studies overruns for Yellow Fever and Marburg Human trial	08/11/2020-09/30/2022	$ 2,896,627

Beginning with the effective date of this modification in ARTICLE I.4. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES ARE INCLUDED IN FULL TEXT AND ADDED TO TERMS

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

As prescribed in 4.2105(b), insert the following clause:

PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2020)

(a) *Definitions.* As used in this clause—*Backhaul* means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (*e.g.,* connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (*e.g.,* fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (*e.g.*, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) *Prohibition.*

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system,

or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) *Exceptions.* This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

52.244-6 Subcontracts for Commercial Items. (Aug 2020)

Subcontracts for Commercial Items

(a) Definitions. As used in this clause— Commercial item and commercially available off-the-shelf item have the meanings contained in Federal Acquisition Regulation (FAR) 2.101. Subcontract includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or non-developmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509), if the subcontract exceeds the threshold specified in FAR 3.1004(a) on the date of subcontract award and has a performance period of more than 120 days. In altering this clause to identify the appropriate parties, all disclosures of violation of the civil False Claims Act or of Federal criminal law shall be directed to the agency Office of the Inspector General, with a copy to the Contracting Officer.

(ii) 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5), if the subcontract is funded under the Recovery Act.

(iii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017).

(iv) 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (Jun 2016), other than subcontracts for commercially available off-the-shelf items, if flow down is required in accordance with paragraph (c) of FAR clause 52.204-21.

(v) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(vi) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(vii) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C.637(d)(2) and (3)), if the subcontract offers further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(viii) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(ix) 52.222-26, Equal Opportunity (Sept 2015) (E.O.11246).

(x) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C.4212(a));

(xi) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C.793).

(xii) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C.4212).

(xiii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496), if flow down is required in accordance with paragraph (f) of FAR clause 52.222-40.

(xiv) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O. 13627).

(B) Alternate I (Mar 2015) of 52.222-50(22 U.S.C. chapter 78 and E.O. 13627).

(xv) 52.222-55, Minimum Wages under Executive Order 13658 (Dec 2015), if flow down is required in accordance with paragraph (k) of FAR clause 52.222-55.

(xvi) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706), if flow down is required in accordance with paragraph (m) of FAR clause 52.222-62.

(xvii) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a) if flow down is required in accordance with 52.224-3(f).

(B) Alternate I (Jan 2017) of 52.224-3, if flow down is required in accordance with 52.224-3(f) and the agency specifies that only its agency-provided training is acceptable).

(xviii) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xix) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Dec 2013), if flow down is required in accordance with paragraph (c) of FAR clause 52.232-40.

(xx) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. App.1241 and 10 U.S.C.2631), if flow down is required in accordance with paragraph (d) of FAR clause 52.247-64).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

END OF MODIFICATION 23 OF HHSN272201300017C

OMB Approval 2700-0042

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
	1		1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
Twenty-three (23)	April 30, 2020		

6. ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Office of Acquisitions
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY *(If other than Item 6)* CODE N/A

MID RCB-A

8. NAME AND ADDRESS OF CONTRACTOR *(No. Street, county, State and ZIP: Code)*

BIOCRYST PHARMACEUTICALS, INC.
4505 EMPEROR BLVD SUITE 200
DURHAM, NC 27703

CODE FACILITY CODE

(□) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSN272201300017C

10B. DATED *(SEE ITEM 13)* September 16, 2013

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER Specify type of modification and authority) Administrative change.

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return __ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

PURPOSE: Change the Contracting Officer Representative (COR). Article G.1 shall remove Helen F Schultz, MS, Ph. D as the COR and replace Michael Kozar, Ph. D. as the COR. All other terms remain the same.

The completion date of the contract is unchanged to September 30, 2022.
Contract cost ceiling is unchanged at $45,931,229

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		John Outen, Contracting Officer Office of Acquisitions, DEA, NIAID, NIH, DHHS	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY John E. Outen -S *(Signature of Contracting Officer)*	16C. DATE SIGNED Digitally signed by John E. Outen -S Date: 2020.09.14 09:26:14 -04'00'

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
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STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

Certain information has been omitted from this exhibit in places marked "[***]" because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

OMB Approval 2700-0042

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ▶	RATING	PAGE	OF PAGES
		N/A	1	46

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75N93020C00055	September 1, 2020	5792458

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 6)	CODE
National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions 5601 Fishers Lane, Room 3D38, MSC 9821 Bethesda, Maryland 20892-9821		MID RCB-A	N/A

7. NAME AND ADDRESS OF CONTRACTOR (No. street, county, state and ZIP Code)	8. DELIVERY	
BioCryst Pharmaceuticals 4505 Emperor Blvd., Suite 200 Durham, N.C. 27703	☐ FOB ORIGIN ☒ OTHER (See below) FOB Destination	
	9. DISCOUNT FOR PROMPT PAYMENT N/A	
	10. SUBMIT INVOICES ADDRESS SHOWN IN:	ITEM Art. G.3

CODE	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
See Section E.	N/A	See Article G.3	N/A

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)(1)

ACCOUNTING AND APPROPRIATION DATA:
COVID-19 Supp 3 CAN #: 20-8044965 Obligate: $6,326,480

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Title: To manufacture and evaluate the safety, efficacy and tolerability of galidesivir a broad spectrum, antiviral therapeutic. **Completion Period**: September 1, 2020 through June 30, 2021. **Contract Type**: Cost Reimbursement plus fixed fee - completion	Base Period			$6,326,480

15G. TOTAL AMOUNT OF CONTRACT ▶ $6,326,480

16. TABLE OF CONTENTS

(✓)	SEC.	DESCRIPTION	PAGE(S)	(✓)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
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☒	B	SERVICES AND COST	4			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
☒	C	DESCRIPTION/SPECS./WORK STATEMENT	6	☒	J	LIST OF ATTACHMENTS	45
☒	D	PACKAGING AND MARKING	13			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
☒	E	INSPECTION AND ACCEPTANCE	13	☒	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	46
☒	F	DELIVERIES OR PERFORMANCE	14				
☒	G	CONTRACT ADMINISTRATION DATA	17	☐	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
☒	H	SPECIAL CONTRACT REQUIREMENTS	20	☐	M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ **CONTRACTOR'S NEGOT**IATED AGREEMENT
(Contractor is required to sign this document and return one electronic copy 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. ☐ AWARD *(Contractor is not required to sign this document.)* Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the **following documents: (a) the Government's solicitation and your offer, and (**b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
Jon P. Stonehouse CEO	Swee L. Teo Contracting Officer, MID RCB-A, OA,DEA,NIAID

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
(Signature of person authorized to sign)	8/28/2020	BY Swee L. Teo -S Digitally signed by Swee L Teo -S Date: 2020.08.31 08:03:02 -04'00' *(Signature of Contracting Officer)*	August 31, 2020

CONTRACT TABLE OF CONTENTS

PART I - THE SCHEDULE

SECTION B - SERVICES AND COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall manufacture and evaluate the safety, efficacy and tolerability of galidesivir a broad spectrum, antiviral therapeutic.

ARTICLE B.2. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $[***].

b. The fixed fee for the Base Period of this contract is $[***]. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $6,326,480.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period	$[***]	$[***]	$6,326,480
Option One	$[***]	$[***]	$[***]
Option Two	$[***]	$[***]	$[***]
Option Three	$[***]	$[***]	$[***]
Option Four	$[***]	$[***]	$[***]
Total [Base Period and Options]	$[***]	$[***]	$43,907,603

ARTICLE B.3. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Accountability and Transparency of COVID-19 Supplemental Funding**

In accordance with the Executive Office of the President, Office of Management and Budget, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116136), federal agencies must accurately record and track funding for awards made under the new relief legislation to ensure accountability and transparency. Agencies must report information on awards to provide the public with information in a clear, accurate, and timely manner. Spending transparency and regular reporting will provide important accountability mechanisms to help safeguard taxpayer dollars. Accurately recording and tracking funding for awards made under the new relief legislation is essential

to providing relief to citizens and businesses, facilitating oversight, and creating accountability for results.

As a recipient of federal supplemental COVID-19 funding under this contract, the Contractor shall:

i. Accurately record and track COVID-19 supplemental funding designated solely for COVID-19 projects under the scope of work of the contract.

ii. Ensure accountability and transparency when claiming costs for reimbursement.

iii. On all invoices submitted for payment to the Government, the Contractor shall track, identify, and segregate supplemental COVID-19 reimbursable costs from non-COVID-19 reimbursable costs.

b. **Establishment of Indirect Cost Rate**

The Contractor may bill overhead costs at a temporary billing rate of [***]% of direct labor plus fringe benefits costs and General and Administrative costs at a temporary billing rate of [***]% of total direct costs; until such time as indirect costs have been established, provided, that the Contractor's indirect cost proposal is submitted to the cognizant office responsible for negotiating indirect costs no later than six (6) months after the date of contract award. If, the indirect cost proposal is not submitted in a timely manner, any temporary indirect costs billed after this due date will be suspended until such time as the indirect cost proposal is submitted.

c. **Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of the information/data that it is provided 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.
Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. 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 Contracting Officer.

d. **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:

Contract No. 75N93020C00055.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

1. Conferences and Meetings

2. Food for Meals, Light Refreshments, and Beverages

3. Promotional Items *[includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.]*

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

5. Special rearrangement or alteration of facilities;

6. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

7. Travel to attend general scientific meetings;

8. Foreign travel;

9. Consultant costs;

10. Subcontracts;

11. Patient care costs;

12. Accountable Government Property (defined as non-expendable personal property with an acquisition cost of $1,000 or more) and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value.

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

b. **Travel Costs**

1. The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.2 - Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. 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, dated August 14, 2020, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

a. **Technical 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 the DELIVERIES Article in SECTION F of this contract:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. **Monthly Progress Report**

   i. This report shall include a description of the technical activities and results during the reporting period, and the activities planned for the ensuing reporting period, and shall include a budget summary for costs incurred during the monthly reporting period for the base period and each option and milestone. The funding level shall be presented in correlation with percent completion of the activities under the base, option and/or milestone.

   ii. 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. Monthly Progress Reports shall not be required when the Annual Progress Report is due.

   iii. This report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract.

2. **Annual Technical Progress Report for Clinical Research Study Populations**

   The Contractor shall submit in accordance with the DELIVERIES Article in SECTION F of the contract information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research,Amended, October 2001 applies. Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

3. **Annual Progress Report**

   i. This report shall include a summation of the technical activities and results for the entire contract period covered, a budget summary for costs incurred during the annual reporting period for the base period and each option and milestone. The funding level shall be presented in correlation with percent completion of the activities under the base, option and/or milestone.

ii. An annual report will not be required for the period when the Final Report is due.

iii. This report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract.

The Contractor shall provide the Contracting Officer with one copy of the Annual Progress Report in **draft** form in accordance with the DELIVERIES Article in SECTION F of this contract. The Contracting Officer's Representative (COR) will review the draft report and provide the Contracting Officer with comments within 15 Calendar days after receipt. The Annual Progress Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

4. **Final Report**

This report is 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 Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. An Annual report will not be required for the period when the Final Report is due.

The Contractor shall provide the Contracting Officer with one copy of the Final Report in **draft** form in accordance with the DELIVERIES Article in SECTION F of this contract. The Contracting Officer's Representative (COR) will review the draft report and provide the Contracting Officer with comments within 15 Calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

5. **Summary of Salient Results**

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 in accordance with the DELIVERIES Article in SECTION F of this contract.

6. **Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents**

For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, the following information shall also be included in each Annual Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

2. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:

    1. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;

    2. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html) or listed on the U.S. National Select Agents Registry restricted experiments website (http://www.selectagents.gov/index.html);

3. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.

4. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Annual Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Annual Progress Report.

b. **Other Reports/Deliverables**

1. **Product Development Plan and Work Plan**

The Contractor shall update the Product Development Plan (PDP) and create a Work Plan to incorporate the progress from the effective date of the contract. The Contractor shall submit an updated PDP for review in accordance with the DELIVERIES Article in SECTION F of this contract and prior to initiation of product development activities, unless otherwise negotiated with the COR and the Contracting Officer. This updated PDP and Work Plan shall include:

i. Clearly defined goals, product development stages and product development activities.

ii. A breakdown of activities by fiscal year and non-severable stages, and applicable decision gates.

iii. Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.

iv. A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a task-linked budget (a budget linked to each major activity). A Gantt chart should be provided to outline the proposed activities.

v. The Work Plan shall include a description of the studies to be performed within each stage of the project. The Contractor shall also be required to submit a revised PDP and associated Work Plan when a change to the approved plans is requested by the COR.

vi. Risk identification, analysis, and mitigation strategies for accomplishing the objectives of this contract within the period of performance, particularly with respect to adverse experimental or production results, new scientific findings or regulatory guidance from FDA.

2. **Milestone Completion / Decision Gate Report**

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a decision point, as defined in the Work Plan for the Implementation of the Staged Product Development Plan and in accordance with the DELIVERIES Article in SECTION F of this contract. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/or conclusions resulting from the

analysis and scientific evaluation of data accumulated to date under the project. Submission of these reports shall coincide with the decision points specified in their Statement of Work.

3. **Audit Reports**

   The Contractor shall submit copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report in accordance with the DELIVERIES Article in SECTION F of this contract.

4. **Final Clinical Trial Protocols**

   NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in the NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award), the Contractor shall develop a protocol and all associated documents for each clinical trial and submit drafts for review as well as all final protocols and protocol amendments for approval by DMID in accordance with the DELIVERIES Article in SECTION F of this contract. Prior to FDA submission and enrollment, additional reviews and approval periods may be required for changes in the final protocol. Three (3) weeks should be planned for each review period. It is recommended that protocols be submitted using approved DMID templates. The DMID templates and other important information regarding performing human subject research are available at https://www.niaid.nih.gov/grants-contracts/human-subjects.

5. **Final Clinical Study Report**

   For each clinical study performed with contract support, a Draft Clinical Study Report shall be provided upon completion of the analysis of all data generated in the clinical trial in accordance with the DELIVERIES Article in SECTION F of this contract . Following review and approval by DMID, final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 and submitted in accordance with the DELIVERIES Article in SECTION F of the contract.

6. **Final Non-Clinical Study Protocols**

   Submit electronic copies of draft protocols for all non-clinical studies in accordance with the DELIVERIES Article in SECTION F of the contract for review and approval by the COR. Allow at least 10 calendar days for review unless otherwise agreed upon by the COR. The non-clinical study protocols shall undergo at least one round of revision and resubmission for final approval. Final Non-Clinical Study Protocols shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract.

7. **Final Non-Clinical Study Reports**

   For each non-clinical study performed with contract support, a Draft Non-Clinical Study Report should be prepared and submitted in accordance with the DELIVERIES Article in SECTION F of the contract. Allow at least one round of revision and resubmission for final approval unless otherwise agreed upon by the COR. The Non-Clinical Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed. Final Non - Clinical Study Reports shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract.

8. **FDA Correspondence and Meetings**

Submit for review and approval planned FDA communications as well as any subsequent correspondence and resulting meeting summaries in accordance with the DELIVERIES Article in Section F of this contract.

9. **Human Subject IRB Annual Report (Form OMB No. 0990-0263)**

   The Contractor shall submit the Human Subject Annual Report in accordance with the DELIVERIES Article in SECTION F of this contract.

10. **Clinical Monitoring Plan**

    For each clinical trial performed with contract support, a Clinical Monitoring Plan should be prepared and submitted in accordance with the DELIVERIES Article in SECTION F of this contract.

11. **Clinical Monitoring Reports**

    A copy of each Clinical Monitoring Report shall be provided in accordance with the DELIVERIES Article of SECTION F of the contract, unless significant GCP violations were discovered in the clinical monitoring visit. If significant GCP violations were discovered, the Contractor will notify the COR as soon as the Contractor learns about the violation, and the Clinical Monitoring Report shall be provided within fifteen (15) calendar days of the completion of the clinical monitoring visit.

12. **Quality Assurance (QA) Reports**

    Upon request of the COR, the Contractor shall provide a copy of the QA report in accordance with the DELIVERIES Article of SECTION F of the contract.

13. **Safety Oversight Reports**

    The Contractor shall provide open (blinded) and closed (unblinded) reports to be reviewed by the safety oversight monitoring board at the intervals specified by the approved clinical protocol. The Contractor shall provide the report in accordance with the DELIVERIES Article of SECTION F of the contract in a format mutually agreed upon. The Contractor shall provide shell reports (without any data) in accordance with the DELIVERIES Article of SECTION F of the contract.

14. **Sample of Products**

    The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding in accordance with the DELIVERIES Article of SECTION F of the contract.

15. **Technology Transfer**

    Technology Transfer packages shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract to include complete protocols and critical, assays or procedures developed and/or improved with contract funding.

16. **Institutional Biosafety Approval**

    The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments in accordance with the DELIVERIES Article in SECTION F of the contract.

17. **Annual Contract Review Meeting**

A report of the Post Award Contract Initiation Meeting and Annual Contract Review Meetings shall be prepared by the Contractor and submitted in accordance with the DELIVERIES Article in SECTION F of the contract. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

18. **Monthly Teleconference and Meeting Minutes**

The Contractor shall arrange and participate in a monthly teleconference with the COR on a day and time to be established. Monthly teleconference minutes as well as ad hoc teleconferences and meetings minutes shall be provided by the Contractor in accordance with the DELIVERIES Article in SECTION F of the contract and include the following:

i. List of action items (including who is responsible for the action item);

ii. Summary of any high-level decisions made during the teleconference;

iii. Summary of concerns raised during the teleconference and the plan to address these concerns.

19. **External Advisory Group Meetings**

Reports of all meetings and communications with the External Advisory Group or its individual members shall be documented and submitted in accordance with the DELIVERIES Article in SECTION F of the contract. Documentation of such meetings/communications shall include a summary of the discussions and copies of slide presentations.

20. **Reporting of Financial Conflict of Interest (FCOI)**

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

45 CFR Part 94 is available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45. See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

(Reference subparagraph g. of the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

21. **Section 508 Annual Report**

The contractor shall submit an annual Section 508 report in accordance with the DELIVERIES Article in SECTION F of this contract. The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.gov/web/508/contracting/technology/vendors.html under "Vendor Information and Documents."

REPORTING REQUIREMENTS FOR USE WITH THE ELECTRONIC REPORT DELIVERABLE SUBMISSION (eRDS) SITE

All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, available at the following website: https://erds.niaid.nih.gov/. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act

of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

ARTICLE C.3. 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, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisition
5601 Fishers Lane
MSC 9821
Bethesda, Maryland 20892- 9821

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 at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

1. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
2. For the purpose of this SECTION, the Contracting Officer's Representative is the authorized representative of the Contracting Officer.
3. Inspection and acceptance will be performed at:
   National Institutes of Health
   National Institute of Allergy and Infectious Diseases
   5601 Fishers Lane
   Rockville, Maryland 20852

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

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

   FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. COMPLETION DATE

1. The completion date of the base requirement of this contract is June 30, 2021.
2. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the completion date will be increased as listed below:

Option	Completion Period
Base	**June 30, 2021**
Option One	**[***]**
Option Two	**[***]**
Option Three	**[***]**
Option Four	**[***]**

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

1. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Progress Reports	One electronic copy via eRDS	On or before 15 calendar days following each reporting period
(2)	Annual Progress Reports	Draft Report - one electronic copy via email Annual Report - one electronic copy via eRDS	Draft Report on or before 30 calendar days prior to each reporting period. Annual Report on or before 30 calendar days following each reporting period.
(3)	Final Report	Draft Report - one electronic copy via email Final Report - One electronic copy via eRDS	Draft Report on or before 45 calendar days prior to contract completion date. Final Report on or before contract completion date.

Item	Description	Quantity	Delivery Schedule
(4)	Summary of Salient Results	One electronic copy via eRDS	On or before contract completion date
(5)	Annual Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents	One electronic copy via eRDS	To be included in each Annual Progress Report. See item 2 above.
(6)	Annual Technical Progress Report for Clinical Research Study Populations	One electronic copy via eRDS	On or before 30 calendar days following the contract anniversary date
(7)	Product Development Plan and Work Plan	One electronic copy via eRDS	Within 30 calendar days from the effective date of the contract and prior to initiation of product development activities.
(8)	Milestone Completion Decision Gate Report	One electronic copy via eRDS	Within 15 calendar days after completion of a stage of product development and a decision point has been reached as defined in the Work Plan.
(9)	Audit Report	One electronic copy via eRDS	Within 30 calendar days of completion of an audit.
(10)	Final Clinical Trial Protocols	Draft protocol - one electronic copy via email Final protocol - one electronic copy via eRDS	Draft protocol on or before 21 calendar days prior to study initiation. Final protocol - within 15 calendar days following approval of final protocol and protocol amendments.
(11)	Final Clinical Study Report	Draft report - one electronic copy via email Final report - one electronic copy via eRDS	Draft Report on or before 30 calendar days after completion of the analysis of all data generated in each clinical study or applicable option completion date, whichever comes first. Final Report on or before applicable option completion date.
(12)	Final Non-Clinical Study Protocols	Draft report - one electronic copy via email Final protocol - one electronic copy via eRDS	Draft protocol on or before 15 calendar days prior to study initiation. Final protocol within 15 calendar days following approval of final protocol and protocol amendments .
(13)	Final Non-Clinical Study Reports	Draft report - one electronic copy via email. Final report - one electronic copy via eRDS.	Draft reports on or before 30 calendar days after completion of each non-clinical study or applicable

Item	Description	Quantity	Delivery Schedule
			option completion date, whichever comes first. Final report on or before applicable option completion date.
(14)	FDA Correspondence and Meetings	One electronic copy via eRDS	Within 5 calendar days of receiving correspondence from or holding meeting with the FDA.
(15)	Human Subject IRB Annual Report	One electronic copy via eRDS	Within 30 calendar days of each anniversary date of the contract
(16)	Clinical Monitoring Plan	One electronic copy via eRDS	On or before 45 calendar days prior to the initiation date of the clinical trial.
(17)	Clinical Monitoring Reports	One electronic copy via eRDS	Within 30 calendar days of the completion of clinical monitoring visit.
(18)	Quality Assurance Report	One electronic copy via eRDS	Within 5 calendar days following COR's request.
(19)	Safety Oversight Report	One electronic copy via eRDS	Within 10 calendar days prior to each board meeting date.
(20)	Sample of Products	As directed by COR	On or before contract completion date.
(21)	Technical Transfer	One electronic copy via eRDS	On or before contract completion date.
(22)	Institutional Biosafety Approval	One electronic copy via eRDS	Within 10 calendar days following approval from Institutional Biosafety Committee Review.
(23)	Annual Contract Review Meeting	One electronic copy via eRDS	Within 21 calendar days following the date of the meetings.
(24)	Monthly Teleconference and Meeting Minutes	One electronic copy via eRDS	Within 5 calendar days following date of the teleconference or meeting.
(25)	External Advisory Group Meetings	One electronic copy via eRDS	Within 21 calendar days following meeting or communications.
(26)	Section 508 Annual Report	One electronic copy via eRDS	Within 15 calendar days following each reporting period.

2. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No	Quantity
CO and COR	Items 1 - 19 and 21 - 26	One electronic copy via eRDS
COR	Item 20	As directed by COR

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/?q=browsefar.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

Michael Kozar, Ph.D.

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) 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 Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

The following individual is considered to be essential to the work being performed hereunder:

Name	Title
William Sheridan, Ph.D.	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following **designated billing office**:

      National Institutes of Health
      Office of Financial Management
      Commercial Accounts
      2115 East Jefferson Street, Room 4B-432, MSC 8500
      Bethesda, MD 20892-8500

   b. The current national emergency and the need to protect Federal and Contractor staff has resulted in a change to NIH's invoice submission process. Effective Wednesday, April 1, 2020, all NIH contractors/vendors invoices should be sent electronically via email to the NIH Office of Financial Management (OFM) and the NIH Contracting Officer (CO) using the electronic submission instructions in accordance with Attachment 2b. - Instructions on Email Submission of Invoices to NIH OFM of the contract.

      On March 30, 2020, Governor Hogan issued a stay-at-home order for the state of Maryland where residents should not leave their homes unless it is for an essential purpose. Stay-at-home orders were also issued by the state of Virginia and the District of Columbia. Therefore, any mailed contractor/vendor invoices will be processed by NIH; however, significant delays are expected due to staff teleworking and complying with the stay-at-home orders. It is important that NIH contractors/vendors follow procedures of Attachment 2b. - Instructions on Email Submission of Invoices to NIH OFM of SECTION J of the contract in order to ensure smooth processing of invoices and timely payment.

   c. One copy of the invoice shall be submitted to the following **approving official**:

      Contracting Officer
      Office of Acquisitions
      DEA, NIAID, NIH
      5601 Fishers Lane
      Bethesda MSC 9821
      Maryland 20892- 9821

      The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include

the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

Central Point of Distribution: NIAID_MIDARCB_Invoices

The Contractor shall include the Central Point of Distribution on the invoice.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases .

   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   d. Invoice Matching Option. This contract requires a two-way match.

   e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

   f. The Contract Title is:

      To manufacture and evaluate the safety, efficacy and tolerability of galidesivir a broad spectrum, antiviral therapeutic.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

   "I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such

payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. 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, Interim evaluation(s) will be prepared annually on the anniversary date of the contract's effective date.

   Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted sixty days 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.

2. Electronic Access to Contractor Performance Evaluations

   Contractors may access evaluations through a secure Web site for review and comment at the following address:

   http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

1. 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 (FWA) 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.

2. 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. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. 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 creating liability on the part of the Government for the acts of the Contractor or its employees.

3. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the

Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

4. 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.

(End of clause)

ARTICLE H.2. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (December 2015)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

ARTICLE H.3. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.4. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.5. GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS

NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training should be refreshed at least every three years to remain current with regulations, standards and guidelines. The Contractor shall provide completion of training documentation to the Contracting Officer's Representative (COR).

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

ARTICLE H.6. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION

The Contractor conducting clinical trials, funded wholly or partially through the NIH extramural and intramural programs, shall ensure that its NIH-funded clinical trials are registered at, and summary results information is submitted to, www.clinicaltrials.gov for public posting. See NIH Guide Notice NOT-OD-16-149 dated September 16, 2016.

All NIH-funded clinical trials shall be registered and results information submitted to www.clinicaltrials.gov regardless of study phase, type of intervention, or whether they are subject to the regulation 42 CFR Part 11. Clinical trials subject to the regulation are called "applicable clinical trials."

The Contractor must submit a plan with its proposal to meet the regulatory requirements of the dissemination of information of NIH-funded Clinical Trials. The Contractor and investigators are required to comply with all terms and conditions of award, including following their acceptable plan for the dissemination of NIH-funded clinical trial information.

The Contractor must register all NIH-funded clinical trials in www.clinicaltrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. The Contractor shall include the trial registration number (NCT number) in the Technical Progress Report covering the period in which registration occurred, and as a standalone notification to the Contracting Officer within ten (10) calendar days of the registration. Each NIH-funded clinical trial must have only one entry in www.ClinicalTrials.gov that contains its registration and results information.

The Contractor shall include a specific statement in all informed consent documents relating to posting of clinical trials information to www.clinicaltrials.gov. The responsibilities of the Contractor will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the Contractor is the responsible party, the Contractor will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the Contractor is not the responsible party, the Contractor will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the Contractor will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical trial record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

The Contracting Officer may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 days.

- Temporary withhold payments pending correction of the deficiency;
- Disallow all or part of the cost of the activity or action not in compliance;
- Wholly or partly suspend or terminate the contract award;
- Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding regulations at 2 CFR part 376;
- Withhold further awards for the project and program;
- Take other remedies that may be legally available.

ARTICLE H.7. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION PLAN

The special terms and conditions in the Contract Award that include a clinical trial:

1. The clinical trial(s) supported by this award is subject to the plan submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan must state that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant. The plan also must state that primary summary results shall be reported in ClinicalTrials.gov, including adverse event information, not later than one year after the primary completion date of the trial. The reporting of summary results is required by this term of award.
2. This award is subject to reporting requirements with each submission of the annual report. Contractor shall agree to the following annual certification. By affirming this annual certification:

The Contractor hereby certifies that all investigators conducting NIH-funded clinical trials under the NIH contract number 75N93020C00055 are in compliance with the Contractor's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded wholly or partially under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date of the trial.

ARTICLE H.8. CERTIFICATE OF CONFIDENTIALITY

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.

Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the NIH Policy for Issuing Certificate of Confidentiality (CoC) NOT-OD-17-109, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act as a term and condition of the contract. The certificate will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate is subject to the requirements of subsection 301(d) of the Public Health Service Act. The Contractor shall ensure that Subcontractors who receive funds to carry out part of the Federal award are subject to subsection 301(d) of the Public Health Service Act and the NIH Policy for Issuing CoC.

ARTICLE H.9. SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For Institutional Review Board (IRB), the Contractor shall use the single Institutional Review Board (sIRB) of record for multi-site research. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the National Institutes of Health (NIH) shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 and the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research. Any IRB serving as the sIRB of record for NIH funded research shall be registered with the HHS Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study.

The Contractor shall provide to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance.

This paragraph applies only if the Government provided a sIRB through a separate entity as stated in section- C. When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the Contracting Officer sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

Exceptions to the NIH Single IRB Policy

The Contractor may request an exception in the following instances:

1. Sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions);
2. *Other exceptions*, to be determined by NIH if there is a compelling justification; and
3. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.

Policy-based exceptions and time limited exceptions are automatically granted when identified in the sIRB Plan.

Other exceptions must be reviewed by NIH sIRB Exceptions Review Committee (ERC) and are expected to be granted rarely. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification-

1. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
2. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
3. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot

serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).

- For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

4. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception*. The Offerors should not assume that an *other exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions*, the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an Other Exception to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO. For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

ARTICLE H.10. PLAN FOR SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For this multi-site study, the Contractor agrees to adhere to the NIH sIRB policy, and the IRB shall serve as the single IRB of record. All participating sites have agreed to rely on the IRB, and a written authorization/reliance agreement shall be developed. Any additional sites added after contract award shall also agree to rely on this study's single IRB of record. Communication plans for interactions between the sIRB and participating sites shall be described in the authorization/reliance agreement. All participating sites shall, prior to initiating the study, sign the authorization/ reliance agreement that shall clarify the roles and responsibilities of the sIRB and participating sites. The Contractor shall maintain records of the authorization/reliance agreements, including the communication plans. The approved sIRB plan will be incorporated as a term and condition of the award. Any updates/changes to the plan shall be provided to the Contracting Officer's Representative with a copy submitted to the Contracting Officer within 30 calendar days.

Exceptions to the Single IRB Plan

The Contractor may request an exception to the sIRB plan under the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions)

*Review by a single IRB of record will not be possible for (**sites)** because of federal/state/tribal law, regulation, or policy (**provide specific citation(s))***

- *Other exceptions*, to be determined by NIH if there is a compelling justification

*Review by a single IRB of record will not be possible for (**this contractor)** because of (**provide compelling justification and rationale why local IRB is uniquely qualified to be the reviewing IRB for the specific site(s**)).*

- Time Limited Exceptions: New multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy.

*Review by a single IRB of record will not be possible for (**sites)** because of ongoing multi-site parent study (**provide parent contract number)**.*

ARTICLE H.11. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The Contractor must submit the results of valid analyses by sex/gender and race/ethnicity to Clinicaltrials.gov for all NIH-conducted or supported applicable NIH-defined Phase III clinical trials. This requirement does not apply to NIH-defined Phase III trials not considered to applicable clinical trials under 42 CFR Part 11. The Contractor must report applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component. The Contractor must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

Note: Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information, including the results of the valid analyses by sex/gender and race/ethnicity, from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of new use is being sought.

ARTICLE H.12. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals

across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The Contractor must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Contractor must provide a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the contractor must provide acceptable justification for the exclusion.

The Contractor must submit cumulative data as prescribed in the Age Enrollment Report template on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

ARTICLE H.13. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database ClinicalTrials.gov. Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.

ARTICLE H.14. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf, Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The Contractor is the Sponsor, therefore the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

Additional information is available at: http://prsinfo.clinicaltrials.gov .

ARTICLE H.15. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform

Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.16. 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 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).

ARTICLE H.17. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.18. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-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, resulting from research supported in whole or in part with direct costs from NIH. NIH 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 NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.19. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

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

(End of clause)

ARTICLE H.20. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.21. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

1. The Contractor shall not use any funds obligated under this contract for any abortion.
2. The Contractor shall not use any funds obligated under this contract for the following:
    a. The creation of a human embryo or embryos for research purposes; or
    b. 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)).
3. 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.
4. The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

ARTICLE H.22. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

ARTICLE H.23. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.24. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.25. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H.26. GUN CONTROL

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

ARTICLE H.27. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST – OPTION Article in SECTION B of this contract.

ARTICLE H.28. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

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

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

3. The Section 508 accessibility standards applicable to this contract are: 1194.31 Functional Performance Criteria and 1194.41 Information, documentation, and support.

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

5. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards.

Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

ARTICLE H.29. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45
As required by 45 CFR Part 94, the Institution shall, at a minimum:

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

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

    1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

    2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

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

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

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

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

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

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

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

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

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

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

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests.. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the

Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

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

ARTICLE H.30. PUBLICATION AND PUBLICITY

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, the Contractor shall acknowledge the support of the National Institutes of Health 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 National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N93020C00055"

a. **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.31. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.32. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH 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. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH 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 Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-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.

ARTICLE H.33. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA).* The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/biosafety/publications/index.htm under "Publications);
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

ARTICLE H.34. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and 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.

ARTICLE H.35. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

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 as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Nov 2013*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*

FAR CLAUSE NO.	DATE	TITLE
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.203-99	Feb 2015	Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)
52.204-13	Oct 2016	System for Award Management Maintenance
52.209-6	Oct 2015	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $750,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $750,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Nov 2016	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)

FAR CLAUSE NO.	DATE	TITLE
52.219-9	Jan 2017	Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Sep 2016	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans ($150,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	May 2014	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs (Over $700,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)

FAR CLAUSE NO.	***DATE***	***TITLE***
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Oct 2010*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Nov 2017*	*Subcontracts for Commercial Items*
52.245-1	*Jan 2017*	*Government Property*
52.245-9	*Apr 2012*	*Use and Charges*
52.246-23	*Feb 1997*	*Limitation of Liability (Over the Simplified Acquisition Threshold)*
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 CLAUSE NO.	***DATE***	***TITLE***
352.203-70	*Dec 2015*	*Anti-Lobbying*
352.222-70	*Dec 2015*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Dec 2015*	*Publications and Publicity*
352.233-71	*Dec 2015*	*Litigation and Claims*
352.237-75	*Dec 2015*	*Key Personnel*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 11/2017].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. *FAR Clause* ***52.215-23, Limitations on Pass-Through Charges*** *(October 2009), is added.*

b. *FAR Clause* ***52.244-6 - Subcontracts for Commercial Items*** *(Aug 2020) is substituted therefor.*

ARTICLE I.3. Additional Contract Clauses

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.

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (October 2015).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (October 2015).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

3. FAR Clause **52.204-14**, **Service Contract Reporting Requirements** (October 2016).

4. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).

5. FAR Clause **52.210-1, Market Research** (April 2011).

6. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

7. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

   "....The Contracting Officer may exercise the option by written notice to the Contractor prior to contract completion date ...."

8. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (October 2014).

   "(c) Waiver of evaluation preference.....
   [ ] Offeror elects to waive the evaluation preference."

9. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

10. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).

11. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

Specific data items that are not subject to paragraph (j) include:None

12. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

13. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).

14. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.208-70, Printing and Duplication** (December 2015)

2. HHSAR Clause **352.211-3, Paperwork Reduction Act** (December 2015)

3. HHSAR Clause **352.223-70, Safety and Health** (December 2015)

4. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

   Note: *The Salary Rate Limitation is at the Executive Level II Rate.*

   See the following website for Executive Schedule rates of pay: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/.

   (*For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.*)

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

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

1. FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (June 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.

2. FAR Clause 52.204-25, **Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment** (Aug 2020)

As prescribed in 4.2105(b), insert the following clause:

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

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (*e.g.*, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (*e.g.*, microwave) or wired (*e.g.*, fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) *Prohibition*.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) *Exceptions*. This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) *Reporting requirement*.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract

are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) *Subcontracts*. The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

3. *FAR Clause* ***52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters*** *(July 2013)*

As prescribed in 9.104-7(c), insert the following clause:

a. *The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at http://www.acquisition.gov.*

b. *As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments--*

1. *The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--*

i. *Government personnel and authorized users performing business on behalf of the Government; or*

ii. *The Contractor, when viewing data on itself; and*

2. *The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--*

i. *Past performance reviews required by subpart 42.15;*

ii. Information that was entered prior to April 15, 2011; or

iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

c. The Contractor will receive notification when the Government posts new information to the Contractor's record.

1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

3. As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

d. Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(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

Statement of Work, dated August 14, 2020, 4 pages.

2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4

a. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)- 4, (7/13), 6 pages.

b. Instructions on Email Submission of Invoices to NIH OFM , April 23 , 2020 , 1 page .

3. Cumulative Inclusion Enrollment Report

PHS Human Subjects and Clinical Trials Information Form/Cumulative Inclusion Enrollment Report, Located at:

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/humansubjectstudy-v1.0.pdf.

4. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (12/15), 2 pages.

5. Research Patient Care Costs

Research Patient Care Costs, NIH(RC)-11, 4/1/84, 1 page.

6. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

   The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

   (End of clause)

END of the SCHEDULE

(CONTRACT)

Certain information has been omitted from this exhibit in places marked "[***]" because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

OMB Approval 2700-0042

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE 1 OF PAGES 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
One (01)	Block 16 b		

6. ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Office of Acquisitions
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY *(If other than Item 6)* CODE N/A

MID RCB-A

8. NAME AND ADDRESS OF CONTRACTOR *(No. Street, county, State and ZIP: Code)*

BIOCRYST PHARMACEUTICALS, INC.
4505 EMPEROR BLVD SUITE 200
DURHAM, NC 27703

CODE FACILITY CODE

(☐) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75N93020C00055

10B. DATED *(SEE ITEM 13)* September 1, 2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER Specify type of modification and authority) FAR 52.217-7, Mutual Agreement of the Parties

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return __ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

PURPOSE: Revise Option 1 to subdivide into Options 1(a)-1(f) with the same cost and fee. Revise completion dates and periods of performance. Incorporate revised Statement of Work to reflect programmatic progress and gateway decisions

The completion date of the contract is unchanged to June 30, 2021.
Contract exercised amount is unchanged at $6,326,480
Contract cost ceiling is unchanged at $43,907,603

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Jon P. Stonehouse, CEO	John Outen, Contracting Officer Office of Acquisitions, DEA, NIAID, NIH, DHHS

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)	10/14/2020	BY John E. Outen -S *(Signature of Contracting Officer)*	Digitally signed by John E. Outen -S Date: 2020.10.14 10:55:32 -04'00'

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STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

Beginning with the effective date of this modification, ARTICLE B.2. ESTIMATED COST – OPTION

ARTICLE B.2. ESTIMATED COST – OPTION 1 is revised and the table is revised to incorporate changes below:

Prism Line		**Estimated Cost ($)**	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Line 1	BASE Period	$[***]	$[***]	$6,326,480
Line 2	Option 1(a)	$[***]	$[***]	$[***]
Line 3	Option 2	$[***]	$[***]	$[***]
Line 4	Option 3	$[***]	$[***]	$[***]
Line 5	Option 4	$[***]	$[***]	$[***]
Line 6	Option 1(b)	$[***]	$[***]	$[***]
Line 7	Option 1(c)	$[***]	$[***]	$[***]
Line 8	Option 1(d)	$[***]	$[***]	$[***]
Line 9	Option 1(e)	$[***]	$[***]	$[***]
Line 10	Option 1(f)	$[***]	$[***]	$[***]
	Total Base Period and all Options	$[***]	$[***]	$43,907,603

ARTICLE C.1. STATEMENT OF WORK

a. 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, dated October 2, 2020, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE F.1. COMPLETION DATE – Option 1 completion period is removed in its entirety. schedule and table are revised to incorporate changes as in the table below:

Period	Completion Period
BASE	June 30, 2021
Option 2	[***]
Option 3	[***]
Option 4	[***]
Option 1 (a)	[***]
Option 1 (b)	[***]
Option 1 (c)	[***]

Option 1 (d)	[***]
Option 1 (e)	[***]
Option 1 (f)	[***]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS
SECTION J - LIST OF ATTACHMENTS

The following documents as revised is attached and incorporated in this contract:

1. Statement of Work

Statement of Work dated October 2, 2020, 5 pages.

END OF MODIFICATION 1 OF 75N93020C00055

Exhibit 10.7

Certain information has been omitted from this exhibit in places marked "[***]" because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

Execution Version

THIRD AMENDMENT TO SECOND AMENDED AND RESTATED CREDIT AND SECURITY AGREEMENT

This THIRD AMENDMENT TO SECOND AMENDED AND RESTATED CREDIT AND SECURITY AGREEMENT (this "**Agreement**") is made as of this 28th day of September, 2020, by and among **BIOCRYST PHARMACEUTICALS, INC.,** a Delaware corporation ("**BioCryst**"), **MDCP, LLC**, a Delaware limited liability company ("**Peramivir SPE**", and together with BioCryst, collectively in the singular, "**Borrower**"), **MIDCAP FINANCIAL TRUST**, as Agent for Lenders (in such capacity and together with its permitted successors and assigns, the "**Agent**") and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders, and Borrower have entered into that certain Second Amended and Restated Credit and Security Agreement, dated as of February 5, 2019 (as amended by that certain First Amendment to Second Amended and Restated Credit and Security Agreement, dated as of September 10, 2019 and that certain Second Amendment to Second Amended and Restated Credit and Security Agreement, dated as of September 13, 2019 and as further amended, restated, supplemented or otherwise modified prior to the date hereof, the "**Original Credit Agreement**" and as the same is amended hereby and as it may be further amended, restated, supplemented or otherwise modified from time to time, the "**Credit Agreement**"), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrower in the amounts and manner set forth in the Credit Agreement.

B. Borrower has requested, and Agent and Lenders constituting at least the Required Lenders have agreed, to amend the Original Credit Agreement, upon the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Required Lenders, and Borrower hereby agree as follows:

1. **Recitals; Construction**. This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as modified hereby. The Recitals set forth above shall be construed as part of this Agreement as if set forth fully in the body of this Agreement. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Amendments to Original Credit Agreement**. Subject to the terms and conditions of this Agreement, including, without limitation, the conditions to effectiveness set forth in Section 4 below, the Original Credit Agreement is hereby amended as follows:

(a) Section 6.8(a) of the Original Credit Agreement is hereby amended and restated in its entirety as follows:

"Borrower shall provide Agent with at least [***] (or such shorter period as Agent may accept in its sole discretion) prior written notice of its intention to create or, to the extent permitted pursuant to this Agreement, acquire a new Subsidiary or Permitted Joint Venture. Upon such creation or, to the extent permitted hereunder, acquisition of any Subsidiary or Permitted Joint Venture, Borrower and such Subsidiary shall promptly (and in any event within [***] of such creation or acquisition) take all such action as may be reasonably required by Agent or the Required Lenders to cause each such Subsidiary (other than a Foreign Subsidiary, an Excluded Domestic Holdco or a Permitted Joint Venture) to either, in the discretion of Agent, become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Financing Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower shall grant and pledge to Agent, for the ratable benefit of the Lenders, a perfected security interest in the stock, units or other evidence of ownership of each Subsidiary and Permitted Joint Venture that is directly owned by Borrower, except to the extent constituting Excluded Property (the foregoing collectively, the "**Joinder Requirements**"); provided that Borrower shall not be permitted to make any Investment in such Subsidiary until such time as Borrower has satisfied the Joinder Requirements, if applicable.

(b) The first sentence of Section 6.8(b) of the Original Credit Agreement is hereby amended and restated in its entirety as follows:

"Borrower further agrees to ensure, and cause each Restricted Subsidiary to ensure, that the total amount of cash and cash equivalents (i) held by BioCryst Ireland Limited and its Subsidiaries, shall not, at any time, exceed [***] and (ii) held by all other Restricted Subsidiaries (other than cash and cash equivalents held by Credit Parties in Collateral Accounts that are subject to Agent's first priority perfected security interest), shall not, at any time, exceed [***].

(c) The following new defined terms are hereby added to Section 15 of the Original Credit Agreement in appropriate alphabetical order:

"**Permitted BioCryst Ireland Investments**" means, so long as no Default or Event of Default shall have occurred and be continuing or result from any such Investment, (a) an initial, one time Investment of cash and cash equivalents made within [***] of the Third Amendment Effective Date in BioCryst Ireland Limited in an amount not to exceed [***], (b) additional Investments of cash and cash equivalents in BioCryst Ireland Limited, but solely to the extent that the aggregate amount of such Investments does not exceed [***] for the twelve (12)-month period immediately preceding the making of any such Investment (excluding, for purposes of such calculation, the amount of the initial Investment made pursuant to clause (a)), and (c) Investments of cash and cash equivalents by BioCryst Ireland Limited in its Subsidiaries.

"**Third Amendment Effective Date**" means September 28, 2020.

(d) Clause (f) of the definition of "**Permitted Investments**" in Section 15 of the Original Credit Agreement is hereby amended and restated in its entirety as follows:

"(f) (i) the Permitted BioCryst Ireland Investments and (ii) other Investments of cash and cash equivalents in (x) Restricted Subsidiaries that are Foreign Subsidiaries, but solely to the extent that the aggregate amount of such Investments does not exceed [***] for the twelve (12)-month period immediately preceding the making of any such Investment, and (y) Restricted Subsidiaries that are Domestic Subsidiaries but solely to the extent that the aggregate amount of such Investments does not exceed [***] for the twelve (12)-month period immediately preceding the making of any such Investment; *provided, however*, that the aggregate amount of such Investments in any Restricted Subsidiary made pursuant to clause (ii) above shall not, in any event, exceed the amount necessary to fund the current operating expenses of such Restricted Subsidiary (taking into account their revenue from other sources);"

3. **Representations and Warranties; Reaffirmation of Security Interest**. Borrower hereby confirms that all of the representations and warranties set forth in the Credit Agreement are true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) with respect to Borrower as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date. Nothing herein is intended to impair or limit the validity, priority or extent of Agent's security interests in and Liens on the Collateral. Borrower acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of Borrower, and are enforceable against Borrower in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors' rights generally and by general equitable principles.

4. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which each of the following conditions has been satisfied, as determined by Agent in its sole discretion:

(a) Agent shall have received (including by way of facsimile or other electronic transmission) a duly authorized, executed and delivered counterpart of the signature page to this Agreement, from Borrower, Agent and the Required Lenders;

(b) all representations and warranties of Borrower contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof, except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (without duplication of any materiality qualifier in the text of such representation or warranty) (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof);

(c) Immediately before and immediately after giving effect to this Agreement, no Default or Event of Default shall have occurred and be continuing or result therefrom; and

(d) Borrower shall have delivered such other documents, information, certificates, records, permits, and filings as the Agent may reasonably request.

5. **Release.** In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Borrower, voluntarily, knowingly, unconditionally and irrevocably, with specific and express intent, for and on behalf of itself and all of its respective parents, subsidiaries, affiliates, members, managers, predecessors, successors, and assigns, and each of their respective current and former directors, officers, shareholders, agents, and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Releasing Parties**") does hereby fully and completely release, acquit and forever discharge each of Agent, Lenders, and each their respective parents, subsidiaries, affiliates, members, managers, shareholders, directors, officers and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Released Parties**"), of and from any and all actions, causes of action, suits, debts, disputes, damages, claims, obligations, liabilities, costs, expenses and demands of any kind whatsoever, at law or in equity, whether matured or unmatured, liquidated or unliquidated, vested or contingent, choate or inchoate, known or unknown that the Releasing Parties (or any of them) has against the Released Parties or any of them (whether directly or indirectly), based in whole or in part on facts, whether or not now known, existing on or before the date hereof. Borrower acknowledges that the foregoing release is a material inducement to Agent's and each Lender's decision to enter into this Agreement and agree to the modifications contemplated hereunder, and has been relied upon by Agent and Lenders in connection therewith.

6. **No Waiver or Novation.** The execution, delivery and effectiveness of this Agreement shall not operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a deemed satisfaction or waiver of any condition precedent to the funding of Credit Facility #2 or Credit Facility #3 or a waiver of any existing Defaults or Events of Default under the Credit Agreement or other Financing Documents or any of Agent's rights and remedies in respect of such Defaults or Events of Default. This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

7. **Affirmation.** Except as specifically amended pursuant to the terms hereof, Borrower hereby acknowledges and agrees that the Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower. Borrower covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the Financing Documents, notwithstanding any prior course of conduct, waivers, releases or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions. Borrower confirms and agrees that all security interests and Liens granted to Agent continue in full force and effect, and all Collateral remains free and clear of any Liens, other than those granted to Agent and Permitted Liens.

8. **Miscellaneous.**

(a) Reference to the Effect on the Credit Agreement. Upon the effectiveness of this Agreement, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of similar import shall mean and be a reference to the Credit Agreement, as modified by this Agreement. Except as specifically set forth above, the Credit Agreement, and all other Financing Documents (and all covenants, terms, conditions and agreements therein), shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower.

(b) THIS AGREEMENT AND THE RIGHTS, REMEDIES AND OBLIGATIONS OF THE PARTIES HERETO AND HERETO, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT, THE RELATIONSHIP OF THE PARTIES, AND/OR THE INTERPRETATION AND ENFORCEMENT OF THE RIGHTS AND DUTIES OF THE PARTIES AND ALL OTHER MATTERS RELATING HERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF MARYLAND, WITHOUT REFERENCE TO ITS CONFLICT OF LAW PROVISIONS. NOTWITHSTANDING THE FOREGOING, AGENT AND LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST EACH CREDIT PARTY OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH AGENT AND LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 12.1 OF THE CREDIT AGREEMENT) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE AGENT'S AND LENDERS' RIGHTS AGAINST SUCH CREDIT PARTY OR ITS PROPERTY. EACH CREDIT PARTY EXPRESSLY SUBMITS AND CONSENTS IN ADVANCE TO SUCH JURISDICTION IN ANY ACTION OR SUIT COMMENCED IN ANY SUCH COURT, AND EACH CREDIT PARTY HEREBY WAIVES ANY OBJECTION THAT IT MAY HAVE BASED UPON LACK OF PERSONAL JURISDICTION, IMPROPER VENUE, OR FORUM NON CONVENIENS AND HEREBY CONSENTS TO THE GRANTING OF SUCH LEGAL OR EQUITABLE RELIEF AS IS DEEMED APPROPRIATE BY SUCH COURT. BORROWER HEREBY WAIVES PERSONAL SERVICE OF THE SUMMONS, COMPLAINTS, AND OTHER PROCESS ISSUED IN SUCH ACTION OR SUIT AND AGREES THAT SERVICE OF SUCH SUMMONS, COMPLAINTS, AND OTHER PROCESS MAY BE MADE BY REGISTERED OR CERTIFIED MAIL ADDRESSED TO THE APPLICABLE CREDIT PARTY AT THE ADDRESS SET FORTH IN ARTICLE 11 OF THE CREDIT AGREEMENT AND THAT SERVICE SO MADE SHALL BE DEEMED COMPLETED UPON THE EARLIER TO OCCUR OF SUCH CREDIT PARTY'S ACTUAL RECEIPT THEREOF OR THREE (3) DAYS AFTER DEPOSIT IN THE U.S. MAIL, PROPER POSTAGE PREPAID.

(c) TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, AGENT AND LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR BOTH PARTIES TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

(d) Incorporation of Credit Agreement Provisions. The provisions contained in Section 13.2 (Indemnification) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(e) Headings. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(f) Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same instrument. Delivery of an executed counterpart of this Agreement by facsimile or by electronic mail delivery of an electronic version (e.g., .pdf or .tif file) of an executed signature page shall be effective as delivery of an original executed counterpart hereof and shall bind the parties hereto.

(g) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(h) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(i) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, the undersigned have executed this Agreement as of the day and year first hereinabove set forth.

AGENT:

MIDCAP FINANCIAL TRUST, a Delaware statutory trust

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem (SEAL)
Name: Maurice Amsellem
Title: Authorized Signatory

LENDERS:

MIDCAP FINANCIAL TRUST

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem (SEAL)
Name: Maurice Amsellem
Title: Authorized Signatory

MIDCAP FUNDING V TRUST, a Delaware statutory trust

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem (SEAL)
Name: Maurice Amsellem
Title: Authorized Signatory

MIDCAP FUNDING XIII TRUST, a Delaware statutory trust

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem (SEAL)
Name: Maurice Amsellem
Title: Authorized Signatory

MIDCAP FUNDING XXX TRUST, a Delaware statutory trust

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem (SEAL)
Name: Maurice Amsellem
Title: Authorized Signatory

LENDERS:

ELM 2020-3 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ John O Dea (SEAL)
Name: John O Dea / Director
Title: Authorized Signatory

ELM 2018-2 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: John O Dea (SEAL)
Name: John O Dea / Director
Title: Authorized Signatory

BORROWER:

BIOCRYST PHARMACEUTICALS, INC.

By: /s/ Alane Barnes (SEAL)
Name: Alane Barnes
Title: Chief Legal Officer

MDCP, LLC

By: /s/ Alane Barnes (SEAL)
Name: Alane Barnes
Title: Chief Legal Officer

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00013	09/29/2020		

6. ISSUED BY CODE ASPR-BARDA

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

7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR-BARDA01

ASPR-BARDA
330 Independence Ave, SW, Rm G644
Washington DC 20201

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

BIOCRYST PHARMACEUTICALS, INC. 726613
BIOCRYST PHARMACEUTICALS, INC.
4505 EMPEROR BLVD STE 200
DURHAM NC 277038457

CODE 726613 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201500007C

10B. DATED *(SEE ITEM 13)* 03/27/2015

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
2015.1992013.25103 Net Decrease: -$74,709.97

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Unilateral modification; Authority: (31 U.S.C. 1553(a))

E. IMPORTANT: Contractor ☒ is not ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 62-1413174
DUNS Number: 618194609
The purpose of this modification is to de-obligate expiring FY 2015 funding for Option 3/CLIN 0004.

The contract funding for Option 3/CLIN 0004 is reduced by $74,709.97 from $119,123.00 to $44,413.03.

All other terms and conditions of the contract remain unchanged.
Appr. Yr.: 2015 CAN: 1992013 Object Class: 25103
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		ROSHAWN K. MAJORS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ *(Signature of person authorized to sign)*		Roshawn K. Simpson *(Signature of Contracting Officer)*	Sept. 29, 2020

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
BIOCRYST PHARMACEUTICALS, INC. 726613

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 03/31/2015 to 05/31/2021				
	Change Item 4 to read as follows(amount shown is the obligated amount):				
4	UDO de-obligation of expiring FY 2015 funding				-74,709.97

Exhibit 31.1

CERTIFICATIONS

I, Jon P. Stonehouse, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioCryst Pharmaceuticals, 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(s) 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 6, 2020

/s/ Jon P. Stonehouse
Jon P. Stonehouse
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Anthony Doyle, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioCryst Pharmaceuticals, 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(s) 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 6, 2020

/s/ Anthony Doyle
Anthony Doyle
Senior Vice President, Chief 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 of BioCryst Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jon P. Stonehouse, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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 result of operations of the Company.

/s/ Jon P. Stonehouse
Jon P. Stonehouse
President and Chief Executive Officer
Date: November 6, 2020

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BioCryst Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony Doyle, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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 result of operations of the Company.

/s/ Anthony Doyle
Anthony Doyle
Senior Vice President, Chief Financial Officer
Date: November 6, 2020