UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from to

Commission File Number: 001-38942

ARCTURUS THERAPEUTICS HOLDINGS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**32-0595345** **(I.R.S. Employer Identification No.)**
10628 Science Center Drive, Suite 250 **San Diego, California** **(Address of principal executive offices)**	**92121** **(Zip Code)**

Registrant's telephone number, including area code: (858) 900-2660

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ARCT	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of November 2, 2022, the registrant had 26,492,869 shares of voting common stock outstanding.

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or this quarterly report, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the documents incorporated by reference herein may contain express or implied "forward-looking statements" within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part II, Item 1A, "Risk Factors" in this quarterly report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as "may," "will," "expect," "anticipate," "intend," "plan," "believe," "estimate" or other words indicating future results, though not all forward-looking statements necessarily contain these identifying words. Forward-looking statements in this quarterly report include, but are not limited to, statements about:

- our compliance, and ability to remain in compliance, with the stringent requirements of our current and potential government contracts, including our arrangements with the Biomedical Advanced Research and Development Authority, a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services and the Department of Defense;
- the status, success and benefits of our arrangements with private and governmental entities, some of which are subject to termination for convenience by our counterparties;
- regulatory filings, submissions and notices related to our commercial arrangements, including those made to the U.S. Federal Trade Commission and Department of Justice pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976;
- the potential effects and benefits of our technologies and product candidates on their own and in comparison to technologies, drugs or courses of treatment currently available or that may be developed by competitors;
- the likelihood that clinical data will be sufficient for regulatory approval;
- the anticipated timing for receipt of data or results of a study or clinical trial, including the anticipated data for our ARCT-810 trial;
- the likelihood or timing of any regulatory approval;
- the potential administration regimen or dosage, or ability to administer multiple doses of, any of our product candidates;
- our plans to research, develop and commercialize our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;
- the rate and degree of market acceptance of our product candidates;
- the success of competing therapies that are or may become available;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- interactions with regulatory authorities in the United States and foreign countries;
- our ability to attract and retain experienced and seasoned scientific and management professionals to lead the Company;
- our strategic alliance partners' election to pursue development and commercialization of any programs or product candidates that are subject to our collaboration and license agreements with such partners;
- the anticipated benefits and success of our collaboration agreement with CSL Seqirus related to the licensure of our STARR™ mRNA technology and LUNAR® lipid-mediated delivery, including our timely receipt of upfront and potential royalty and other payments thereunder;
- our ability to attract collaborators with relevant development, regulatory and commercialization expertise;
- future activities to be undertaken by our strategic alliance partners, collaborators and other third parties;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our ability to avoid, settle or be victorious at costly litigation with shareholders, former executives or others, should these situations arise;
- our ability to obtain and deploy funding for our operations and to efficiently use our financial and other resources;

- our ability to continue as a going concern; and
- the accuracy of our estimates regarding future expenses, future revenues, capital requirements and need for additional financing.

These and other forward-looking statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. In addition, historic results of scientific research, preclinical and clinical trials do not guarantee that future research or trials will suggest the same conclusions, nor that historic results referred to herein will be interpreted in the same manner due to additional research, preclinical and clinical trial results or otherwise. The forward-looking statements contained in this quarterly report are subject to risks and uncertainties, including those discussed in our other filings with the United States Securities and Exchange Commission, or the Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof unless specifically stated otherwise. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)	September 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 237,676	$ 370,492
Accounts receivable	2,044	3,367
Prepaid expenses and other current assets	6,960	5,102
Total current assets	246,680	378,961
Property and equipment, net	11,347	5,643
Operating lease right-of-use asset, net	33,519	5,618
Equity-method investment	—	515
Non-current restricted cash	2,081	2,077
Total assets	$ 293,627	$ 392,814
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 17,962	$ 10,058
Accrued liabilities	25,529	23,523
Current portion of long-term debt	27,702	22,474
Deferred revenue	4,656	43,482
Total current liabilities	75,849	99,537
Deferred revenue, net of current portion	5,179	19,931
Long-term debt, net of current portion	32,038	40,633
Operating lease liability, net of current portion	31,218	4,502
Other non-current liabilities	3,676	—
Total liabilities	$ 147,960	$ 164,603
Stockholders' equity		
Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 26,492 at September 30, 2022 and 26,372 at December 31, 2021	26	26
Additional paid-in capital	601,129	575,675
Accumulated deficit	(455,488)	(347,490)
Total stockholders' equity	145,667	228,211
Total liabilities and stockholders' equity	$ 293,627	$ 392,814

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

(in thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 13,369	$ 2,437	$ 45,706	$ 6,565
Operating expenses:				
Research and development, net	37,688	45,398	120,770	141,127
General and administrative	12,488	10,860	34,211	30,645
Total operating expenses	50,176	56,258	154,981	171,772
Loss from operations	(36,807)	(53,821)	(109,275)	(165,207)
Gain (loss) from equity-method investment	—	(250)	(515)	670
Gain from foreign currency	1,862	506	3,237	923
Finance expense, net	(321)	(519)	(1,445)	(1,397)
Net loss	$ (35,266)	$ (54,084)	$ (107,998)	$ (165,011)
Net loss per share, basic and diluted	$ (1.33)	$ (2.05)	$ (4.09)	$ (6.27)
Weighted-average shares outstanding, basic and diluted	26,467	26,338	26,423	26,302
Comprehensive loss:				
Net loss	$ (35,266)	$ (54,084)	$ (107,998)	$ (165,011)
Comprehensive loss	$ (35,266)	$ (54,084)	$ (107,998)	$ (165,011)

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
BALANCE – December 31, 2021	**26,372**	**$ 26**	**$ 575,675**	**$ (347,490)**	**$ 228,211**
Net loss	—	—	—	(51,169)	(51,169)
Share-based compensation expense	—	—	7,371	—	7,371
Issuance of common stock upon exercise of stock options	35	—	336	—	336
BALANCE – March 31, 2022	**26,407**	**$ 26**	**$ 583,382**	**$ (398,659)**	**$ 184,749**
Net loss	—	—	—	(21,563)	(21,563)
Share-based compensation expense	—	—	7,274	—	7,274
Issuance of common stock upon exercise of stock options	27	—	257	—	257
BALANCE – June 30, 2022	**26,434**	**$ 26**	**$ 590,913**	**$ (420,222)**	**$ 170,717**
Net loss	—	—	—	$ (35,266)	(35,266)
Share-based compensation expense	—	—	9,436	—	9,436
Issuance of common stock upon exercise of stock options	36	—	369	—	369
Issuance of common stock under equity plans	22	—	411	—	411
BALANCE – September 30, 2022	**26,492**	**$ 26**	**$ 601,129**	**$ (455,488)**	**$ 145,667**

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY – (Continued)
(unaudited)

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
BALANCE – December 31, 2020	**26,192**	**$ 26**	**$ 540,343**	**$ (143,816)**	**$ 396,553**
Net loss	—	—	—	(56,346)	(56,346)
Issuance of common stock related to acquired in-process research and development	75	—	5,000	—	5,000
Share-based compensation expense	—	—	6,987	—	6,987
Issuance of common stock upon exercise of stock options	52	—	413	—	413
BALANCE – March 31, 2021	**26,319**	**$ 26**	**$ 552,743**	**$ (200,162)**	**$ 352,607**
Net loss	—	—	—	(54,581)	(54,581)
Share-based compensation expense	—	—	7,540	—	7,540
Issuance of common stock upon exercise of stock options	8	—	82	—	82
BALANCE – June 30, 2021	**26,327**	**$ 26**	**$ 560,365**	**$ (254,743)**	**$ 305,648**
Net loss	—	—	—	(54,084)	(54,084)
Share-based compensation expense	—	—	6,870	—	6,870
Issuance of common stock upon exercise of stock options	9	—	177	—	177
Issuance of common stock under equity plans	13	—	515	—	515
BALANCE – September 30, 2021	**26,349**	**$ 26**	**$ 567,927**	**$ (308,827)**	**$ 259,126**

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)	Nine Months Ended September 30, 2022	2021
OPERATING ACTIVITIES:		
Net loss	$ (107,998)	$ (165,011)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	976	883
Share-based compensation expense	24,081	21,397
Acquired in-process research and development expense	—	5,000
Loss (gain) from equity-method investment	515	(670)
Foreign currency transaction gain	(2,976)	(923)
Other non-cash expenses	3,899	2,477
Changes in operating assets and liabilities		
Accounts receivable	1,323	110
Prepaid expense and other assets	(1,858)	(2,302)
Accounts payable	5,335	(2,569)
Accrued liabilities	2,015	13,569
Deferred revenue	(53,578)	35,493
Net cash used in operating activities	(128,266)	(92,546)
INVESTING ACTIVITIES:		
Acquisition of property and equipment	(3,919)	(2,288)
Net cash used in investing activities	(3,919)	(2,288)
FINANCING ACTIVITIES:		
Proceeds from debt	—	46,599
Proceeds from exercise of stock options	962	672
Proceeds from the issuance of common stock under equity plans	411	515
Payments on debt obligations	(2,000)	—
Net cash used in (provided by) financing activities	(627)	47,786
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(132,812)	(47,048)
Cash, cash equivalents and restricted cash at beginning of the period	372,569	463,002
Cash, cash equivalents and restricted cash at end of the period	$ 239,757	$ 415,954

	Nine Months Ended September 30, 2022	2021
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 585	$ 514
Non-cash investing activities		
Right-of-use assets acquired through operating leases	$ 30,191	$ 1,828
Acquisition of in-process research and development through issuance of common stock	$ —	$ 5,000
Purchase of property and equipment in accounts payable and accrued expenses	$ 2,761	$ 60

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

Note 1. Description of Business, Basis of Presentation and Summary of Significant Accounting Policies

Description of Business

Arcturus Therapeutics Holdings Inc. (the “Company” or "Arcturus") is a global late-stage clinical messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases. The Company became a clinical stage company during 2020 when it announced that its Investigational New Drug (“IND”) application for ornithine transcarbamylase (“OTC”) deficiency and its Clinical Trial Application (“CTA”) for candidate LUNAR-COV19 were approved by applicable health authorities.

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Arcturus and its subsidiaries and are unaudited. All intercompany accounts and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management’s opinion, the accompanying condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results for the interim periods presented.

Interim financial results are not necessarily indicative of results anticipated for the full year. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021.

These condensed consolidated financial statements are prepared in accordance with GAAP, which requires management to make estimates and assumptions regarding the valuation of debt instruments, the equity-method investment, share-based compensation expense, accruals for liabilities, income taxes, revenue and deferred revenue, leases, and other matters that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on management’s knowledge of current events and actions the Company may undertake in the future, actual results may ultimately differ from these estimates and assumptions.

Joint Ventures, Equity Method Investments and Variable Interest Entities

Investments for which the Company exercises significant influence, but does not have control are accounted for under the equity method. Equity method investment activity is related to a 49% joint venture with Axcelead, Inc. (see the following paragraph for further details) and an 7% ownership in Vallon Pharmaceuticals, Inc. (see “*Note 10, Related Party Transactions*” for further details). The Company’s share of the investees’ results is presented as either income or loss from equity method investees in the accompanying condensed consolidated statements of operations and comprehensive loss.

In April 2021, Arcturus and Axcelead, Inc., a company existing under the laws of Japan (“Axcelead”), formed a joint venture entity, named Arcalis, Inc. (“JV Entity”), which operates as a corporation under the laws of Japan. Axcelead is an integrated drug discovery solutions provider to the pharmaceutical industry in Japan. On July 1, 2017, Axcelead became the successor to a portion of the drug discovery research department of Takeda Pharmaceutical Company Limited. The goal of the JV Entity is to be a contract development and manufacturing organization focused on mRNA manufacturing that would provide manufacturing services to the Company and also to third parties. The joint venture includes a shareholders agreement which sets forth initial funding of the JV Entity and rights of the JV Entity shareholders, including certain approval rights of Arcturus. As part of the joint venture, the Company entered into a License and Technology Transfer Agreement with the JV Entity, pursuant to which Arcturus grants to JV Entity a nonexclusive license to certain intellectual property for use at the JV Entity’s facilities, and obligates Arcturus to conduct certain technology transfer activities.

The Company consolidates variable interest entities (“VIEs”) where it has been determined that the Company is the primary beneficiary of those entities’ operations. Management believes that power is shared between Arcturus and Axcelead, as unrelated parties. The consent of each of the parties is substantive and is required to make the decisions about the JV Entity’s significant activities. Management does not believe that Arcturus has the power to direct the activities of the JV Entity that most significantly impact the JV Entity’s economic performance. Therefore, the Company concluded it is not required to consolidate the JV Entity under the VIE model.

The equity method of accounting is applicable for the JV Entity as the Company does not own more than 50% of voting power, but has influence over the operation and financial policies of the investee. The Company accounts for its investment in the JV Entity using the equity method of accounting as specified in Accounting Standard Codification ("ASC") 323, Investments — Equity Method and Joint Ventures. Under ASC 323, equity method investments are recorded initially at cost. The Company's initial investment in the JV Entity totaled $9.2 million. However, the JV Entity paid back the Company's initial investment of $9.2 million as an upfront fee/consideration for the License and Technology Transfer Agreement. In substance, there was no cash consideration paid by the Company for its 49% equity interest in the JV Entity.

Liquidity

The Company has incurred significant operating losses since its inception. As of September 30, 2022 and December 31, 2021, the Company had an accumulated deficit of $455.5 million and $347.5 million, respectively.

The Company's activities since inception have consisted principally of research and development activities, general and administrative activities, and raising capital. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before the Company achieves sustainable revenues and profit from operations. From the Company's inception through September 30, 2022, the Company has funded its operations principally with the proceeds from the sale of capital stock, revenues earned through collaboration agreements and proceeds from long-term debt.

At September 30, 2022, the Company's balance of cash and cash equivalents, including restricted cash, was $239.8 million.

Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these condensed consolidated financial statements were available to be issued. There can be no assurance that the Company will be successful in securing additional funding, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Segment Information

In making decisions regarding resource allocation and assessing performance, the chief operating decision-maker identifies operating segments as components of an enterprise for which separate discrete financial information is available for evaluation. The Company and its chief operating decision-maker view the Company's operations and manage its business in one operating segment, which is the research and development of medical applications for the Company's nucleic acid-focused technology.

Revenue Recognition

The Company determines revenue recognition for arrangements within the scope of Topic 606 by performing the following five steps: (i) identify the contract; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the Company satisfies a performance obligation.

The terms of the Company's revenue agreements include license fees, upfront payments, milestone payments, reimbursement for research and development activities, option exercise fees, transfer of drug substance, consulting and related technology transfer fees and royalties on sales of commercialized products. Arrangements that include upfront payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs obligations under these arrangements. The event-based milestone payments represent variable consideration, and the Company uses the most likely amount method to estimate this variable consideration because the Company will either receive the milestone payment or will not, which makes the potential milestone payment a binary event. The most likely amount method requires the Company to determine the likelihood of earning the milestone payment. Given the high degree of uncertainty around achievement of these milestones, the Company determines the milestone amounts to be fully constrained and does not recognize revenue until the uncertainty associated with these payments is resolved. The Company will recognize revenue from sales-based royalty payments when or as the sales occur. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

A performance obligation is a promise in a contract to transfer a distinct good or service to the collaborative partner and is the unit of account in Topic 606. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

Leases

See *"Note 9, Commitments and Contingencies"* for specific details surrounding the Company's leases.

Research and Development, Net

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, share-based compensation, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services), in process research and development expenses and license agreement expenses, net of any grants, and prelaunch inventory. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs related to patient enrollment are accrued as patients enter and progress through the trial.

Pre-Launch Inventory

Prior to obtaining initial regulatory approval for an investigational product candidate, the Company expenses costs relating to production of inventory as research and development expense in its condensed consolidated statements of operations and comprehensive loss, in the period incurred. When the Company believes regulatory approval and subsequent commercialization of an investigational product candidate is probable, and the Company also expects future economic benefit from the sales of the investigational product candidate to be realized, it will then capitalize the costs of production as inventory.

Statement of Cash Flows

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the condensed consolidated balance sheet to the total of the same such amounts shown in the condensed consolidated statement of cash flows:

(in thousands)	September 30, 2022	September 30, 2021
Cash and cash equivalents	$ 237,676	$ 413,880
Non-current restricted cash	2,081	2,074
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 239,757	$ 415,954

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock method.

No dividends were declared or paid during the reported periods.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on our condensed consolidated financial statements and disclosures.

Note 2. Revenue

The Company has entered into license agreements and collaborative research and development arrangements with pharmaceutical and biotechnology companies, as well as consulting, related technology transfer, drug substance transfer and product revenue agreements. Under these arrangements, the Company is entitled to receive license fees, consulting fees, product fees, technological transfer fees, upfront payments, milestone payments if and when certain research and development milestones or technology transfer milestones are achieved, royalties on approved product sales and reimbursement for research and development activities. The Company's costs of performing these services are included within research and development expenses. The Company's milestone payments are typically defined by achievement of certain preclinical, clinical, and commercial success criteria. Preclinical milestones may include in vivo proof of concept in disease animal models, lead candidate identification, and completion of IND-enabling toxicology studies. Clinical milestones may, for example, include successful enrollment of the first patient in or completion

of Phase 1, 2 and 3 clinical trials, and commercial milestones are often tiered based on net or aggregate sale amounts. The Company cannot guarantee the achievement of these milestones due to risks associated with preclinical and clinical activities required for development of nucleic acid medicine-based therapeutics and vaccines.

The following table presents changes during the nine months ended September 30, 2022 in the balances of contract assets, including receivables from collaborative partners, consulting and related technology transfer partners, and contract liabilities, including deferred revenue, as compared to what was disclosed in the Company's Annual Report.

(in thousands)	Contract Assets
BALANCE - December 31, 2021	$ 3,367
Additions for revenue recognized from billings	1,700
Deductions for cash collections	(3,023)
BALANCE – September 30, 2022	$ 2,044

(in thousands)	Contract Liabilities
BALANCE - December 31, 2021	$ 63,413
Additions for advanced billings	1,700
Reclassifications to accrued liabilities	(9,572)
Deductions for promised services provided in current period	(45,706)
BALANCE – September 30, 2022	$ 9,835

The following table summarizes the Company's revenues for the periods indicated (in thousands).

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(Dollars in thousands)	2022	2021	2022	2021
Vinbiocare	$ 11,237	$ 600	$ 26,815	$ 600
Janssen	934	636	2,593	2,229
Ultragenyx	928	926	2,814	2,776
CureVac	225	241	673	713
Israel Ministry of Health	—	—	12,500	—
Other	45	34	311	247
Total revenue	$ 13,369	$ 2,437	$ 45,706	$ 6,565

The following paragraphs provide information regarding the nature and purpose of the Company's most significant collaboration arrangements.

Vinbiocare

During 2021 the Company entered into certain agreements with Vinbiocare, a member of Vingroup Joint Stock Company, whereby the Company would provide technical expertise and support services to Vinbiocare to assist in the build out of a mRNA drug product manufacturing facility in Vietnam. The Company received an upfront payment in aggregate of $40.0 million as part of the Vinbiocare Agreement. In October 2022, the Company and Vinbiocare executed a letter agreement terminating the Technology License and Technical Support Agreement and the Framework Drug Substance Supply Agreement (collectively, the "License & Supply Agreements"). The Company incurred no financial penalties in connection with the termination of the License & Supply Agreements and has no further financial obligations to Vinbiocare under these terminated agreements.

In association with the termination of the License & Supply Agreements, the Company signed in October 2022 the Study Support Agreement with Vinbiocare which provides for Vinbiocare to continue serving as the regulatory and financial sponsor of clinical studies conducted in Vietnam of ARCT-154. To support the continuing activities of these studies, the Study Support Agreement further provides for the Company to conduct certain services and to compensate Vinbiocare to help achieve the objectives of these studies.

The Company has determined that the execution of the Study Support Agreement constitutes a type 1 subsequent event and the impact to the transaction price should be recognized as of September 30, 2022, as the contract negotiations began during the third quarter of 2022 and the conditions existed as of September 30, 2022 although not finalized until October 2022. The Company has reserved a portion of the original upfront payment to be paid to Vinbiocare over the future periods pursuant to the Study Support Agreement by reclassifying a portion of the upfront payment received from Vinbiocare pursuant to the License & Supply Agreements,

from deferred revenue to short-term and long-term liabilities, based on the anticipated timing of the payments to Vinbiocare, and removed that portion of the upfront payment from the transaction price of the modified arrangement. The transaction price was not adjusted for payments that are contingent upon the occurrence of future regulatory or sales related events based on the information currently available to the Company.

The Company has concluded that is has no remaining performance obligations as of September 30, 2022, and therefore has recognized the remaining transaction price of $11.2 million as revenue during the period ended September 30, 2022. As of September 30, 2022, the Company has accrued liabilities related to this arrangement of $5.9 million in current liabilities and $3.7 million in non-current liabilities that will be paid upon the occurrence of specified events through the first quarter of 2025. Vinbiocare is also eligible to receive a single digit percentage of amounts from net sales, if any, of ARCT-154 (or next-generation COVID vaccine) up to a capped amount of low single digit millions. The Company had no remaining deferred revenue as of September 30, 2022. As of December 31, 2021, the deferred revenue balance was $37.2 million.

Janssen Pharmaceuticals, Inc., Ultragenyx Pharmaceutical Inc., CureVac AG

For each of Janssen Pharmaceuticals, Inc. (“Janssen”), Ultragenyx Pharmaceutical Inc. (“Ultragenyx”) and CureVac AG (“CureVac”), the Company evaluated the respective agreement in accordance with ASC Topic 606. The Company concluded that the contract counterparty is a customer. The Company identified all promised goods/services within each agreement, and concluded that the promised goods/services are incapable of being distinct and consequently do not have any value on a standalone basis. Accordingly, the promised goods/services within each agreement were determined to represent a single performance obligation. Lastly, the Company concluded that any options to select additional collaboration targets and to license rights to selected targets were not priced at a discount and therefore do not represent performance obligations for which the transaction price would be allocated.

Janssen

In October 2017, the Company entered into a research collaboration and license agreement with Janssen (the “2017 Agreement”) to collaborate on developing candidates for treating HBV with RNA therapeutics. The 2017 Agreement allocated discovery, development, funding obligations, and ownership of related intellectual property among the Company and Janssen.

As of September 30, 2022, the remaining transaction price consisting of upfront consideration received, budgeted reimbursable out-of-pocket costs and a preclinical milestone payment of $1.0 million received in the fourth quarter of 2021, is expected to be recognized using an input method over the remaining research period. None of the remaining development and commercialization milestones were included in the transaction price as they are outside the control of the Company and contingent upon success in future clinical trials and the collaborator’s efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable, and the Company has no remaining promised goods/services, as such sales were determined to relate predominantly to the license granted to Janssen and therefore have also been excluded from the transaction price.

Total deferred revenue as of September 30, 2022 and December 31, 2021 for Janssen was $6.0 million and $6.3 million, respectively.

On October 31, 2022, Janssen delivered to the Company notice of termination of the 2017 Agreement. The termination is effective 60 days after notice. The Company will not incur any penalties as a result of this termination.

Ultragenyx

In October 2015 the Company entered into a research collaboration and license agreement with Ultragenyx (as amended, the “Ultragenyx Agreement”), whereby Arcturus granted to Ultragenyx a co-exclusive license to certain Arcturus technology, which is in effect only during the reserve target exclusivity term as discussed in the following paragraphs. This collaboration agreement was amended in 2017, 2018 and during the second quarter of 2019. During the initial phase of the collaboration, the Company will design and optimize therapeutics for certain rare disease targets. Ultragenyx has the option under the Ultragenyx Agreement to add additional rare disease targets during the collaborative development period. Additionally, during the collaborative development period, the Company will participate with Ultragenyx in a joint steering committee.

The current potential development, regulatory and commercial milestone payments for the existing development targets as of September 30, 2022 are $138.0 million. Ultragenyx will pay royalties as a single-digit percentage of net sales on a product-by-product and country-by-country basis during the applicable royalty term. As of September 30, 2022, Ultragenyx is working to identify and enroll patients in a Phase 1/2 study.

As of September 30, 2022, the transaction price included the upfront consideration received, option payments, exclusivity extension payments and additional consideration received pursuant to Amendment 3 of the Ultragenyx Agreement ("Amendment 3"). The Company recognizes the reimbursement of labor and expenses as costs are incurred and none of the development and commercialization milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that the consideration is outside the control of the Company and contingent upon success in future clinical trials, approval from the FDA and the collaborator's efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur as they are constrained, provided that the reported sales are reliably measurable and the Company has no remaining promised goods/services, as such sales were determined to relate predominantly to the license granted to Ultragenyx and therefore have also been excluded from the transaction price. During the three months ended September 30, 2022, no adjustments were made to the transaction price.

Amendment 3 was deemed a contract modification and accounted for as part of the original Ultragenyx Agreement. The transaction price is recognized to revenue on a straight-line basis using an input method over the 4-year reserve target exclusivity period. The reserve target exclusivity period represents the timing over which promised goods/services will be provided. Total deferred revenue at September 30, 2022 and December 31, 2021 from Ultragenyx was $2.8 million and $5.5 million, respectively.

CureVac

In January 2018, the Company entered into a Development and Option Agreement (the "Development and Option Agreement") with CureVac. Under the terms of the Development and Option Agreement, the parties agreed to conduct joint preclinical development programs once CureVac makes a payment to pull down a target on the basis of which CureVac is granted options for taking a license on pre-agreed license terms to develop and commercialize certain products incorporating the Company's patents and know-how related to LUNAR® delivery technology (the "Arcturus Delivery Technology"), and CureVac patents and know-how related to mRNA technology.

As of September 30, 2022, the transaction price included the upfront consideration received. The Company recognizes the reimbursement of labor and expenses as costs are incurred and none of the development and commercialization milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the collaborator's efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur as they are constrained, provided that the reported sales are reliably measurable and the Company has no remaining promised goods/services, as such sales were determined to relate predominantly to the license granted to CureVac and therefore have also been excluded from the transaction price. As of September 30, 2022, no adjustments were made to the transaction price.

The upfront consideration of $5.0 million was recorded as deferred revenue in the Company's condensed balance sheet upon receipt and is currently being recognized as revenue on a straight-line basis using an input method over the remaining 10 month contractual term as of September 30, 2022. Total deferred revenue as of September 30, 2022 and December 31, 2021 for CureVac was $0.7 million and $1.4 million, respectively.

Other Agreements

In January 2022, the Company entered into an agreement with a pharmaceutical company, whereby the pharmaceutical company agreed to fund up to $25 million for a clinical trial for a LUNAR-COV19 vaccine candidate as a booster. The Company submitted billings from a third party of $4.9 million related to the clinical trial which falls under the expected funding of $25 million of the booster program. The Company received the $4.9 million reimbursement for the billings subsequent to September 30, 2022. The Company has not recognized any revenue associated with this agreement as of September 30, 2022.

Israeli Ministry of Health

On August 17, 2020, the Company entered into an agreement with the Israeli Ministry of Health (the "MOH") to supply the Company's COVID-19 vaccine candidate to Israel (the "Israel Supply Agreement") subject to certain conditions, including applicable regulatory approvals. In October 2020, and in association with the Israel Supply Agreement, the Company received a non-refundable payment of $12.5 million from the MOH. This payment of $12.5 million is associated with a specified clinical trial milestone and serves as an initial reserve payment for a specified number of doses of the LUNAR-COV19 vaccine candidate pursuant to the Israel Supply Agreement. As a result of the making of this payment, the MOH became bound to purchase an initial quantity of 500,000 reserved vaccine doses, as set forth in and subject to the terms and conditions of the Israel Supply Agreement. Furthermore, the Israel Supply Agreement permitted termination by the MOH immediately upon written notice to Arcturus if the Company did not obtain certain regulatory approvals by December 31, 2021. On April 14, 2022, Arcturus received notice from the MOH to terminate the Israel Supply Agreement. Therefore, the Company recognized the payment as revenue during the second quarter of 2022 as there were no

remaining performance obligations under the agreement. No termination penalties were incurred by the Company connection therewith.

Note 3. Grant Revenue

BARDA Grant

In August 2022, the Company entered into a cost reimbursement contract with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) for an award of up to $63.2 million for the development of a pandemic influenza vaccine using the Company's STARR™ self-amplifying mRNA vaccine platform technology. The Company earns grant revenue for performing tasks under the agreement.

The Company determined that the agreement with BARDA is not in the scope of ASC 808 or ASC 606. Applying International Accounting Standards No. 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance, by analogy, the Company recognizes grant revenue from the reimbursement of direct out-of-pocket expenses, overhead allocations and fringe benefits for research costs associated with the grant. The costs associated with these reimbursements are reflected as a component of research and development expense in the Company’s condensed consolidated statements of operations.

We recognized an immaterial amount of revenue during the three months ended September 30, 2022, which is included in revenue on the Company's condensed consolidated statements of operations. As of September 30, 2022, the remaining available funding net of revenue earned was $63.2 million.

Note 4. Fair Value Measurements

The Company establishes the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company established a fair value hierarchy based on the inputs used to measure fair value.

The three levels of the fair value hierarchy are as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which little or no market data exists and are therefore determined using estimates and assumptions developed by the Company, which reflect those that a market participant would use.

The carrying value of cash, restricted cash, accounts receivable, accounts payable, accrued liabilities and the Singapore loan approximate their respective fair values due to their relative short maturities. The carrying amounts of long-term debt for the amount drawn on the Company’s debt facility approximates fair value as the interest rate is variable and reflects current market rates.

As of September 30, 2022 and December 31, 2021, all assets measured at fair value on a recurring basis consisted of cash equivalents and money market funds, which were classified within Level 1 of the fair value hierarchy. The fair value of these financial instruments was measured based on quoted prices.

Note 5. Balance Sheet Details

Property and equipment, net balances consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Research equipment	$ 8,584	$ 6,735
Computers and software	1,038	488
Office equipment and furniture	958	574
Leasehold improvements	2,486	44
Construction in progress	3,513	2,058
Total	16,579	9,899
Less accumulated depreciation and amortization	(5,232)	(4,256)
Property and equipment, net	$ 11,347	$ 5,643

Depreciation and amortization expense was $0.4 million and $0.3 million for the three months ended September 30, 2022 and 2021, and $1.0 million and $0.9 million for the nine months ended September 30, 2022 and 2021, respectively. Construction in progress primarily includes research equipment that is expected to be placed into service during 2022.

Accrued liabilities consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Accrued compensation	$ 7,802	$ 3,578
Cystic Fibrosis Foundation liability (Note 9)	—	2,777
Current portion of operating lease liability	3,783	1,537
Clinical accruals	2,026	8,675
Vinbiocare contractual liabilities	5,896	—
Other accrued research and development expenses	6,022	6,956
Total	$ 25,529	$ 23,523

Note 6. Debt

Manufacturing Supply Agreement

On November 7, 2020, the Company's wholly-owned subsidiary, Arcturus Therapeutics, Inc., entered into a Manufacturing Support Agreement (the "Support Agreement") with the Economic Development Board of the Republic of Singapore (the "EDB"). Pursuant to the Support Agreement, the EDB agreed to make a term loan (the "Singapore Loan") of S$62.1 million to the Company, subject to the satisfaction of customary deliveries, to support the manufacture of the LUNAR-COV19 vaccine candidate (ARCT-021). The Singapore Loan accrues interest at a rate of 4.5% per annum calculated on a daily basis. The Company elected to borrow the full amount available under the Support Agreement of S$62.1 million ($46.6 million) on January 29, 2021. The EDB agreed to an extension of the reconciliation period to March 31, 2022, with unused funds as of such date returned to the EDB within 30 days following the completion of the customary audit and signed amendment of the Singapore Loan. This audit is scheduled to be completed during the fourth quarter of 2022. During the third quarter of 2022, the Company reported a portion of the Singapore Loan as current to reflect a potential principal repayment that is pending audit completion of approximately S$20.9 million ($15.7 million) in fiscal year 2022 based on amounts not used towards the manufacture of ARCT-021, and expects to refund this portion in the first quarter of fiscal year 2023.

The Singapore Loan was initially recorded as long-term debt at $46.6 million, the amount of cash proceeds at the time the Company received the funding. During the first quarter of 2022, accrued interest of $1.9 million related to 2021 was added to the principal debt balance in accordance with the terms of the Support Agreement and the balance was adjusted to reflect the current exchange rate resulting in an increase in the debt balance to $47.8 million. The Company recorded a net foreign currency transaction gain of $3.0 million for the nine months ended September 30, 2022 compared to a net foreign currency transaction gain of $0.9 million for the nine months ended September 30, 2021. For the three and nine months ended September 30, 2022, the Company recorded interest expense and a corresponding liability of $0.5 million and $1.6 million, respectively, compared to interest expense and a corresponding liability of $0.5 million and $1.4 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2022, the Company was in compliance with all covenants under the Singapore Loan and related commitments.

Long-term debt with Western Alliance Bank

On October 12, 2018, Arcturus Therapeutics, Inc. entered into the loan with Western Alliance Bank (the "Bank"), whereby it received $10.0 million (the "Loan").

The Loan is collateralized by all of the assets of Arcturus Therapeutics, Inc., excluding intellectual property, which is subject to a negative pledge. The Loan contains customary conditions of borrowing, events of default and covenants, including covenants that restrict Arcturus Therapeutics, Inc.'s ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of its capital stock. In addition, Arcturus Therapeutics, Inc. is required to maintain at least 100% of its consolidated, unrestricted cash, or $15.0 million, whichever is lower, with the Bank.

On October 30, 2019, Arcturus Therapeutics, Inc. and the Bank entered into a Third Amendment (the "Third Amendment") to the Loan (as amended, the "Loan Agreement").

Pursuant to the amendment, the Bank agreed to make a term loan to Arcturus Therapeutics, Inc. on October 30, 2019, in the amount of $15.0 million (the "Term Loan"). The resulting net increase in the indebtedness of Arcturus Therapeutics, Inc. was $5.0 million. The Term Loan bears interest at a floating rate ranging from 1.25% to 2.75% above the prime rate. The amendment further provides that the Term Loan has a maturity date of October 30, 2023. Arcturus Therapeutics, Inc. will make monthly payments of interest only until October 1, 2021. The Fourth Amendment was executed in connection with the Singapore Loan. In October of 2021, the Company and the Bank entered into a Fifth Amendment to Loan Agreement that provided for a six month extension to the interest only period which moved the first principal payment to May 1, 2022. In April of 2022, the Company and the Bank entered into a Sixth Amendment to Loan Agreement that provided for a three month extension to the interest only period which moved the first principal payment to August 1, 2022.

Arcturus Therapeutics, Inc. paid a loan origination fee of $54,000 which was recorded as a debt discount along with the remaining loan origination fee from the Loan and is being accreted over the term of the Term Loan. In addition, Arcturus Therapeutics, Inc. is required to pay a fee of $525,000 upon certain change of control events.

The Term Loan may be prepaid in full at any time, subject to a prepayment fee ranging from 0.50% to 2.00% of the prepaid principal amount depending upon the date of the prepayment.

Upon maturity or prepayment (as previously discussed), Arcturus Therapeutics, Inc. will be required to pay a 2% fee as a result of the FDA's approval to proceed with the Company's LUNAR-OTC program based on its IND submission. Such fee is accreted to the long-term debt balance using the effective interest method over the term of the Loan Agreement.

Should an event of default occur, including the occurrence of a material adverse effect, the Company could be liable for immediate repayment of all obligations under the Loan Agreement. As of September 30, 2022, the Company was in compliance with all covenants under the Loan Agreement.

Principal payments, including the final payment due at repayment, on the long-term debt are as follows as of September 30, 2022:

(in thousands)		
2022	$	3,000
2023		10,300
Total	$	13,300

The Company recognized interest expense related to its long-term debt of $0.7 million during each of the three months ended September 30, 2022 and 2021, and $2.1 million and $2.0 million during the nine months ended September 30, 2022 and 2021, respectively.

Note 7. Stockholders' Equity

Alexion Pharmaceuticals License Agreement

On February 17, 2021, the Company entered into an exclusive license agreement with Alexion Pharmaceuticals, Inc. ("Alexion") pursuant to which Alexion granted to the Company an exclusive, worldwide license to exploit certain specified Alexion patent applications. In accordance with the terms of the license agreement, and in exchange for the license, the Company issued 74,713 shares of its common stock to Alexion on February 19, 2021 valued at approximately $5.0 million. The number of shares issued under the agreement was calculated by dividing (i) five million dollars ($5.0 million) by (ii) the volume-weighted average price per share of the Company's common stock on the Nasdaq Global Market for the thirty (30) trading days immediately preceding the effective date of the license agreement (rounded to the nearest whole share). The Company recorded the transaction as an asset purchase as management concluded that all of the value received was related to a single identifiable asset. Further, the Company concluded that there was no alternative future use for the asset and recorded a charge at the closing of the transaction for the full $5.0 million value assigned to the shares issued in connection with the license agreement. This non-cash charge was recorded as acquired in-process research and development expense in the statements of operations and comprehensive loss.

Net Loss per Share

Dilutive securities that were not included in the calculation of diluted net loss per share for the three and nine months ended September 30, 2022 as they were anti-dilutive totaled 507,021 and 650,144, respectively, and 1,457,223 and 1,514,023 for the three and nine months ended September 30, 2021.

Note 8. Share-Based Compensation Expense

In June 2022 at the Company's 2022 Annual Meeting of Stockholders (the "2022 Annual Meeting"), the stockholders of the Company approved an amendment to the Company's 2019 Omnibus Equity Incentive Plan (as amended, the "2019 Plan") which, among other things, increases the aggregate number of shares authorized for use in making awards to eligible persons under the 2019 Plan by 3,750,000 shares, for a total of up to 8,750,000 shares available for issuance. On June 30, 2022, the Company filed a Form S-8 with the Commission to register the issuance of up to 3,750,000 additional shares following the 2022 Annual Meeting. As of September 30, 2022, a total of 3,490,857 shares remain available for future issuance under the 2019 Plan, subject to the terms of the 2019 Plan.

In October 2021, the Company adopted the 2021 Inducement Equity Incentive Plan which covers the award of up to 1,000,000 shares of common stock (the "2021 Plan") effective as of October 15, 2021. Approval of the Company's stockholders will not be required as a condition to the effectiveness of the 2021 Plan for so long as the plan is in compliance with applicable Nasdaq inducement plan rules. On October 20, 2021, the Company filed a Form S-8 with the Commission to register the issuance of up to 1,000,000 shares underlying awards under the 2021 Plan. In April 2022, the compensation committee of the Company's board of directors approved a proposal to reduce the total number of shares available for future issuance under the 2021 Plan to 130,000. As of September 30, 2022, a total of 70,400 shares remain available for future issuance under the 2021 Plan, subject to the terms of the 2021 Plan.

Stock Options

Share-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2022 and 2021 was as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Research and development	$ 3,996	$ 3,304	$ 10,811	$ 10,132
General and administrative	5,440	3,566	13,270	11,265
Total	$ 9,436	$ 6,870	$ 24,081	$ 21,397

Note 9. Income Taxes

The Company is subject to taxation in the United States and various states. The Company computes its quarterly income tax provision by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The primary difference between the effective tax rate and the federal statutory tax rate relates to the valuation allowances on the Company's net operating losses.

For the three and nine months ended September 30, 2022 and 2021, the Company recorded no income tax expense. No tax benefit was provided for losses incurred in United States because those losses are offset by a full valuation allowance.

Note 10. Commitments and Contingencies

COVID-19 Vaccine Development

On March 4, 2020, the Company was awarded a grant ("Grant 1") from the Singapore EDB to support the co-development of a potential COVID-19 vaccine with the Duke-NUS Medical School. The Grant provides for up to S$14.0 million (approximately US$10.0 million using the exchange rate at the time the grant contract was entered into) in grants to support the development of the vaccine. The Grant has been paid in full by the EDB as a result of the achievement of certain milestones related to the progress of the development of the vaccine, as set forth in the award agreement. The funds received have been recognized as contra research and development expense. The parties are in continued negotiations with respect to amendments of Grant 1. Currently, the Company is liable for certain expenses during the program and is also subject to certain conditions including the requirement to pay an agreed upon royalty rate to Duke-NUS on future net sales of the LUNAR-COV19 ARCT-021 vaccine candidate developed with Duke-NUS in markets or jurisdictions outside of Singapore. The Company did not recognize any contra expense related to Grant 1 for the three months ended September 30, 2022 or 2021. The Company did not recognize any contra expense for the nine months ended September

30, 2022, but recognized $1.3 million of contra expense for the nine months ended September 30, 2021 related to Grant 1. As of September 30, 2022 and December 31, 2021, no amount remained in accrued expenses.

On October 2, 2020, the Company was awarded another grant ("Grant 2") from the Singapore EDB to support the clinical development of a potential COVID-19 vaccine (ARCT-021). The grant provides for up to S$9.3 million (approximately US$6.7 million) to support the clinical development of the vaccine candidate for costs incurred in Singapore subject to certain conditions. The grant is paid in two installments upon the achievement of certain milestones related to the progress of the development of the vaccine candidate. The Company received the first installment of $3.6 million in the fourth quarter of 2020. The funds received are recognized as contra research and development expense as costs are incurred. During 2021, the Company recognized the remaining amount of the first installment as contra research and development expense for Grant 2. During the first quarter of 2022, the Company and EDB concluded negotiations on this Contract, and thereby reduced the overall amount received by the Company under the Grant to the first installment of $3.6 million. The EDB agreed to an extension of the reconciliation period to March 31, 2022, with unused funds as of such date returned to the EDB within 30 days following the completion of the customary audit and signed amendment of the Singapore Loan. The audit and amendment is expected to be completed during the fourth quarter of 2022.

Cystic Fibrosis Foundation Agreement

On August 1, 2019, the Company amended its Development Program Letter Agreement, dated May 16, 2017 and as amended July 13, 2018, with the Cystic Fibrosis Foundation ("CFF"). Pursuant to the amendment, (i) CFF increased the amount it will award to advance LUNAR-CF to $15.0 million from approximately $3.2 million, (ii) the Company will provide $5.0 million in matching funds for remaining budgeted costs, (iii) the related disbursement schedule from CFF to Arcturus will be modified such that (a) $4.0 million will be disbursed upon execution of the CFF Amendment, (b) $2.0 million will be disbursed within 30 days of the first day of each of January, April, July and October 2020 upon Arcturus invoicing CFF to meet project goals, and (c) the last payment of $3.0 million less the prior award previously paid out, equaling approximately $2.3 million, will be disbursed upon Arcturus Sub invoicing CFF to meet good manufacturing practices and opening an Investigational New Drug ("IND") application. The funds received from CFF are recognized as contra research and development expense in proportion to the percentage covered by CFF of the overall budget. For the three months ended September 30, 2022 and 2021, the Company recognized contra expense of $0.5 million and $1.6 million, respectively, and for the nine months ended September 30, 2022 and 2021, the Company recognized contra expense of $2.7 million and $3.1 million, respectively. As of September 30, 2022 and December 31, 2021, $0.0 million and $2.8 million, respectively, remained in accrued liabilities.

Leases

In October 2017, the Company entered into a non-cancellable operating lease agreement for office space adjacent to its previously occupied headquarters. The commencement of the lease began in March 2018 and the lease extends for approximately 84 months from the commencement date with a remaining lease term through March 2025. Monthly rental payments are due under the lease and there are escalating rent payments during the term of the lease. The Company is also responsible for its proportional share of operating expenses of the building and common areas. In conjunction with the new lease, the Company received free rent for four months and received a tenant improvement allowance of $74,000. The lease may be extended for one five-year period at the then current market rate with annual escalations; however, the Company deemed the extension option not reasonably certain to be exercised and therefore excluded the option from the lease terms. The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of $96,000 upon executing the lease which is included (along with additional funds required to secure the letter of credit) in the balance of non-current restricted cash.

In February 2020, the Company entered into a second non-cancellable operating lease agreement for office space near its current headquarters. The lease extended for 13 months from the commencement date and included a right to extend the lease for one twelve-month period. In February 2021, the Company opted to extend the lease through March 2025 to coincide with the lease term of the Company's headquarters.

In February 2021, the Company entered into a third non-cancellable operating lease agreement for office space near its current headquarters. The lease extends for 12 months from the commencement date with monthly base rent of approximately $11,000. During the third quarter of 2021, the Company opted to extend the lease for an additional 12 months.

In September 2021, the Company entered into a fourth non-cancellable lease agreement for office, research and development, engineering and laboratory space near its current headquarters. The initial term of the lease will extend ten years and eight months from the date of possession, and the Company will have the right to extend the term of the lease for an additional five-year period. When the lease term was determined for our operating lease right-of-use assets and lease liabilities, the extension option for the lease was not included. The lease has a monthly base rent ranging from $268,000 to $360,000 which escalates over the lease term. The Company received a free rent period of four months and also pays for various operating costs, including utilities and real property taxes. The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of $2.0 million upon

executing the lease which is included (along with additional funds required to secure the letter of credit) in the balance of non-current restricted cash. The lease term commenced during the second quarter of 2022.

Operating lease right-of-use asset and liability on the condensed consolidated balance sheets represent the present value of remaining lease payments over the remaining lease terms. The Company does not allocate lease payments to non-lease components; therefore, payments for common-area-maintenance and administrative services are not included in the operating lease right-of-use asset and liability. The Company uses its incremental borrowing rate to calculate the present value of the lease payments, as the implicit rate in the lease is not readily determinable.

As of September 30, 2022, the remaining payments of the operating lease liability were as follows:

(in thousands)	Remaining Lease Payments
2022	$ 1,338
2023	5,482
2024	5,646
2025	4,019
2026	3,603
Thereafter	23,282
Total remaining lease payments	43,370
Less: imputed interest	(8,369)
Total operating lease liabilities	$ 35,001
Weighted-average remaining lease term	9.0 years
Weighted-average discount rate	5.0%

Operating lease costs consist of the fixed lease payments included in operating lease liability and are recorded on a straight-line basis over the lease terms. Operating lease costs were $1.4 million and $0.5 million for the three months ended September 30, 2022 and 2021, respectively, and $3.3 million and $1.4 million for the nine months ended September 30, 2022 and 2021, respectively.

Note 11. Related Party Transactions

Equity-Method Investment

In June 2018, the Company completed the sale of its intangible asset related to the ADAIR technology. Pursuant to the asset purchase agreement for ADAIR, the Company received a 30% ownership interest in the common stock of Vallon Pharmaceuticals, Inc. (“Vallon”) in consideration for the sale of the ADAIR technology. The Company has no requirement to invest further in Vallon. Vallon completed an initial public offering and began trading on The Nasdaq Stock Market under the ticker “VLON” in February 2021. Additionally, Vallon executed the sale of 3,700,000 shares of common stock through a private placement in May 2022 as well as an exercise of warrants for 2,220,000 shares of common stock in August 2022. As a result, Arcturus owns 843,750 shares of Vallon, or approximately 7%. Based on the Company’s ownership and the Vallon board of directors seat held by an executive of Arcturus, the Company has the ability to exercise significant influence over the operating and financial policies of Vallon; therefore, the Company accounts for this investment as an equity-method investment. The Company accounts for its share of the earnings or losses of the investee with a reporting lag of three months, as the financial statements of the investee are not completed on a basis that is sufficient for the Company to apply the equity method on a current basis. The warrant exercise was at a share price of $0.94, greater than the initial investment which resulted in the Company recording a gain in its equity-method investment. Using a three month lag, the gain has been fully offset by losses incurred by Vallon through June 30, 2022.

See *“Note 1, Joint Ventures, Equity Method Investments and Variable Interest Entities”* for specific details surrounding the Company’s agreement with Axcelead to form the joint venture entity, Arcalis, Inc.

Note 12. Subsequent Events

CSL Seqirus

On November 1, 2022, the Company entered into a collaboration and license agreement (the "Collaboration Agreement”) with Seqirus, Inc., a part of CSL Limited (“CSL Seqirus”), one of the world’s leading influenza vaccine providers, for the research, development, manufacture and global commercialization of self-amplifying mRNA vaccines.

CSL Seqirus will receive exclusive global access to Arcturus’ technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other globally prevalent respiratory infectious diseases. Specifically, the Collaboration Agreement grants CSL Seqirus a license to Arcturus’ STARRTM mRNA technology and LUNAR® lipid-mediated delivery, as well as mRNA drug substance and drug product manufacturing expertise. CSL Seqirus would also receive global non-exclusive access to Arcturus’

intellectual property rights in the field of pandemic preparedness (i.e., pathogens identified as priority diseases by the World Health Organization), with the right to convert to an exclusive license.

Arcturus will receive an upfront payment of $200 million. Arcturus will be eligible to potentially receive development milestones totaling more than $1.3 billion if all products are registered in the licensed fields. Arcturus will also be entitled to potentially receive up to $3 billion in commercial milestones based on “net sales” of vaccines in the various fields. In addition, Arcturus is entitled to receive a 40% share of net profits from COVID-19 vaccine sales and up to low double digit royalties of annual net sales for vaccines against influenza and the other three specified infectious disease pathogens, as well as royalties on revenues from vaccines that may be developed for pandemic preparedness. Entitlement to all such payments is subject to the strict conditions, requirements, royalties reduction provisions and other limitations set forth in the Collaboration Agreement.

The Collaboration Agreement sets forth how the Company and CSL Seqirus shall collaborate to research and develop vaccine candidates. In the COVID-19 field, the Company will lead activities for certain regulatory filings for ARCT-154 in the US and Europe and for research and development activities of a next-generation COVID vaccine candidate. CSL Seqirus will lead and be responsible for all other research and development in COVID-19, influenza and the other fields. Arcturus will provide to CSL Seqirus a credit over five years to offset expenses of research and development activities (but not against milestone payments) on non-COVID-19 programs that Arcturus conducts at the request of CSL Seqirus. CSL Seqirus will have the sole right to commercialize any products that may be developed.

The Collaboration Agreement will not become effective until expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. Either party may terminate the agreement on a field-by-field basis for material breach by the other party, following notice and opportunity to cure. CSL Seqirus may also terminate the Collaboration Agreement in its entirety or on a field-by-field basis for any reason or no reason whatsoever, but may not exercise this termination “for convenience” of the entire agreement or with respect to the influenza field prior to the first commercial sale of a “vaccine product” in the US, Japan, Australia or specified European countries. The Collaboration Agreement may also be terminated by CSL Seqirus for safety reasons, clinical data nonviability, commercial nonviability and other specified reasons.

The Collaboration Agreement allows the Company to fulfill its obligations under its award from the Biomedical Advanced Research and Development Authority (BARDA) relating to rapid pandemic influenza response and announced by the Company in August 2022.

Janssen

On October 31, 2022, Arcturus received notice of termination from Janssen Pharmaceuticals, Inc. of the Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Janssen Pharmaceuticals, Inc., dated October 18, 2017 (the “Janssen Agreement”). The Janssen Agreement provided for the parties to collaborate on developing nucleic acid-based therapeutic candidates for the treatment of Hepatitis B. The Janssen Agreement was terminated in its entirety by Janssen for convenience. Arcturus will not incur any penalties as a result of this termination. The termination is effective 60 days after notice.

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

The following is a discussion of the financial condition and results of operations of Arcturus Therapeutics Holdings Inc. for the three and nine month period ended September 30, 2022. Unless otherwise specified herein, references to the "Company," "Arcturus," "we," "our" and "us" mean Arcturus Therapeutics Holdings Inc. and its consolidated subsidiaries. You should read the following discussion and analysis together with the interim condensed consolidated financial statements and related notes included elsewhere herein. For additional information relating to our management's discussion and analysis of financial conditions and results of operations, please see our Annual Report on Form 10-K for the year ended December 31, 2021 (the "2021 Annual Report"), which was filed with the U.S. Securities and Exchange Commission (the "Commission") on March 1, 2022. Unless otherwise defined herein, capitalized words and expressions used herein shall have the same meanings ascribed to them in the 2021 Annual Report.

This report includes forward-looking statements which, although based on assumptions that we consider reasonable, are subject to risks and uncertainties which could cause actual events or conditions to differ materially from those currently anticipated and expressed or implied by such forward-looking statements.

You should read this report and the documents that we reference in this report and have filed as exhibits to this report completely and with the understanding that our actual future results may be materially different from what we expect. You should also review the factors and risks we describe in the reports we will file or submit from time to time with the Commission after the date of this report.

Overview

Arcturus is a global late-stage clinical messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases. In addition to our messenger RNA ("mRNA") platform, our proprietary lipid nanoparticle delivery system, LUNAR®, has the potential to enable multiple nucleic acid medicines, and our proprietary self-amplifying mRNA technology (Self-Transcribing and Replicating RNA or STARR™) technology has the potential to provide longer-lasting RNA and sustained protein expression at lower dose levels.

We are leveraging our proprietary platform relating to LUNAR® and our nucleic acid technologies to develop and advance a pipeline of mRNA-based vaccines and therapeutics for the prevention of infectious diseases and treatment of rare genetic disorders with significant unmet medical needs. We continue to expand this platform with innovative delivery solutions that allow us to expand our discovery efforts. Our proprietary LUNAR® technology is intended to address major hurdles in RNA drug development, such as the effective and safe delivery of RNA therapeutics to disease-relevant target tissues and for RNA vaccines the mitigation of challenges associated with cold chain storage and distribution via lyophilization. We believe the versatility of our platform to target multiple tissues, its compatibility with various nucleic acid therapeutics, and our expertise in developing scalable manufacturing processes will allow us to deliver on the next generation of nucleic acid medicines.

The following chart represents our current pipeline of Partnered mRNA Therapeutics and Vaccines:

Franchise	Candidate	Partner	Indication	Stage
Hepatic	LUNAR-GSD3 (UX053)	ultragenyx pharmaceutical	Glycogen Storage Disease Type III	Phase 1/2*
Vaccine	LUNAR-COV19 (ARCT-154)	CSL	Endemic COVID-19	Phase 3
	LUNAR-FLU (Seasonal)	CSL	Influenza (seasonal)	Preclinical
	LUNAR-FLU (Pandemic)	BARDA	Influenza (pandemic)	Preclinical

* https://www.sec.gov/Archives/edgar/data/1515673/000095017022013411/rare-20220630.htm

Key Updates on our Vaccine Program

On November 1, 2022, we announced a strategic collaboration with CSL Seqirus, one of the world's leading influenza vaccine providers, for the development, manufacture, and global commercialization of self-amplifying mRNA vaccines. CSL Seqirus is part of CSL Limited.

The collaboration combines CSL Seqirus' established global vaccine commercial and manufacturing infrastructure with Arcturus' manufacturing expertise and innovative STARR™ self-amplifying mRNA vaccine and LUNAR® delivery platform technologies. Arcturus' manufacturing expertise and innovative STARR™ self-amplifying mRNA vaccine and LUNAR® delivery platform technologies have enabled the Company's low dose, lyophilized and durable self-amplifying mRNA vaccines against COVID.

Summary of CSL Seqirus Collaboration

Under the terms of the agreement, CSL Seqirus will receive exclusive global access to Arcturus' technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other globally prevalent respiratory infectious diseases. Specifically, the Collaboration Agreement grants CSL Seqirus a license to Arcturus' STARR mRNA technology and LUNAR lipid-mediated delivery, as well as mRNA drug substance and drug product manufacturing expertise. CSL Seqirus will also receive global non-exclusive access to Arcturus' intellectual property rights in the field of pandemic preparedness (i.e., pathogens identified as priority diseases by the World Health Organization), with the right to convert to an exclusive license. CSL Seqirus will lead manufacturing scale up and commercialization of approved vaccines. The collaboration plans to advance our current LUNAR-COV19 and LUNAR-FLU vaccine programs, as well as three other globally prevalent respiratory infectious diseases.

Arcturus will receive $200 million upfront and is eligible to receive over $1.3 billion in development milestones and over $3 billion in commercial milestones. In addition, the Company is eligible to receive a 40% net profit share for COVID vaccine products and up to low double-digit royalties for vaccines against flu and three other respiratory pathogens.

Arcturus will receive mid-single-digit royalties of any Advance Purchase Agreement (APAs) contracts consummated by CSL Seqirus with government and related entities that use Arcturus technology.

Arcturus will also receive up to low double-digit royalties on sales for vaccines developed with Arcturus technology for use against pathogens listed in the World Health Organization (WHO) Blueprint List of Priority Diseases or declared a Public Health Emergency of International Concern (PHEIC) as part of Seqirus' pandemic preparedness efforts.

Key Updates on Arcturus-Owned mRNA Therapeutic Development Candidates

The following chart represents our current pipeline of Arcturus-Owned mRNA Therapeutic Candidates:

Franchise	Candidate	Funded By	Indication	Prevalence	Stage	Upcoming Milestone
Hepatic	LUNAR-OTC (ARCT-810)	ARCTURUS therapeutics	Ornithine Transcarbamylase Deficiency	> 10,000	Phase 2	Interim Data 2023
Respiratory	LUNAR-CF (ARCT-032)	CYSTIC FIBROSIS FOUNDATION	Cystic Fibrosis	85,000-100,000	PCC	CTA Filing Q4 2022

PCC = Preclinical Candidate; CTA = Clinical Trial Application

- LUNAR-OTC/ARCT-810 - Our rare disease program for ornithine transcarbamylase (OTC) deficiency is continuing to advance. With the increased availability of COVID-19 vaccines and the corresponding reduction of restrictions, there was a significant uptick in recruitment and enrollment activity for the Phase 1b ascending-dose study of ARCT-810 in 12 adults with OTC deficiency. Dosing of the first, second and third cohorts (0.2 mg/kg, 0.3 mg/kg and 0.4mg/kg) has completed, and the fourth cohort (0.5 mg/kg) is being added to the study. In addition, health authorities in the UK, Belgium, Sweden and Spain have approved a randomized, double-blind, placebo-controlled, nested single and multiple ascending dose Phase 2 study of ARCT-810 in 24 adolescent and adult patients with OTC-deficiency. Screening has begun and dosing is expected to begin in Q4 2022. On July 18, 2022, Orphan Drug Designation was granted in the EU by the European Commission based on a positive opinion issued by the EMA.
- LUNAR-CF/ARCT-032 – Our preclinical program for cystic fibrosis is being supported in part by the Cystic Fibrosis Foundation. Results from preclinical studies demonstrate robust protein expression in respiratory epithelium treated with

LUNAR-mRNA in vitro and in vivo. Further, CF human bronchial epithelial cells treated with ARCT-032 in vitro demonstrate restoration of CFTR activity. Nonclinical studies also support advancement of ARCT-032 into clinical development. We expect to file an application for a first-in-human study for ARCT-032, our mRNA therapeutic candidate for CF, by year end.

Key Updates on our Research and Platform Activities

- We continue to conduct exploratory platform development activities, including the evaluation of genome editing, and new targeting approaches, where our LUNAR® and STARR™ platforms could potentially be useful for identification and development of additional products for our portfolio.

Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Report and our audited financial statements and related notes for the year ended December 31, 2021. Our historical results of operations and the year-to-year comparisons of our results of operations that follow are not necessarily indicative of future results.

Revenue

We enter into arrangements with pharmaceutical and biotechnology partners and government agencies that may contain upfront payments, license fees for research and development arrangements, research and development funding, milestone payments, option exercise and exclusivity fees, royalties on future sales, consulting fees and payments for technology transfers. The following table summarizes our total revenues for the periods indicated (in thousands):

	Three Months Ended September 30,		2021 to 2022	
(in thousands)	**2022**	**2021**	**$ change**	**% change**
Revenue	$ 13,369	$ 2,437	$ 10,932	*

	Nine Months Ended September 30,		2021 to 2022	
(in thousands)	**2022**	**2021**	**$ change**	**% change**
Revenue	$ 45,706	$ 6,565	$ 39,141	*

* *Greater than 100%*

Revenue increased by $10.9 million during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. The increase in revenue primarily relates to an increase in revenue of $10.6 million related to the agreement with Vinbiocare.

Revenue increased by $39.1 million during the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. The increase in revenue primarily relates to an increase in revenue of $26.2 million related to the agreement with Vinbiocare and an increase of $12.5 million related to the recognition of reservation fees from the Israeli MOH.

Our operating expenses consist of research and development and general and administrative expenses.

	Three Months Ended September 30,		2021 to 2022		Nine Months Ended September 30,		2021 to 2022	
(in thousands)	**2022**	**2021**	**$ change**	**% change**	**2022**	**2021**	**$ change**	**% change**
Operating expenses:								
Research and development, net	$ 37,688	$ 45,398	$ (7,710)	-17.0%	$ 120,770	$ 141,127	$ (20,357)	-14.4%
General and administrative	12,488	10,860	1,628	15.0%	34,211	30,645	3,566	11.6%
Total	$ 50,176	$ 56,258	$ (6,082)	-10.8%	$ 154,981	$ 171,772	$ (16,791)	-9.8%

Research and Development Expenses, net

The following table presents our total research and development expenses by category:

(in thousands)	Three Months Ended September 30, 2022	2021	2021 to 2022 $ change	2021 to 2022 % change	Nine Months Ended September 30, 2022	2021	2021 to 2022 $ change	2021 to 2022 % change
External pipeline development expenses:								
LUNAR-COVID, net	$ 16,018	$ 29,392	$ (13,374)	-45.5 %	$ 60,774	$ 85,790	$ (25,016)	-29.2 %
LUNAR-OTC, net	2,063	1,478	585	39.6 %	6,471	6,631	(160)	-2.4 %
Early stage programs	2,801	727	2,074	285.3 %	7,031	3,601	3,430	95.3 %
Discovery technologies	3,680	3,708	(28)	-0.8 %	8,287	17,259	(8,972)	-52.0 %
External platform development expenses:								
Personnel related expenses	$ 11,013	$ 8,719	$ 2,294	26.3 %	$ 31,862	$ 24,191	$ 7,671	31.7 %
Facilities and equipment expenses	2,113	1,374	739	53.8 %	6,345	3,655	2,690	73.6 %
Total research and development expenses, net	$ 37,688	$ 45,398	$ (7,710)	-17.0 %	$ 120,770	$ 141,127	$ (20,357)	-14.4 %

Our research and development expenses consist primarily of external manufacturing costs, in-vivo research studies and clinical trials performed by contract research organizations, clinical and regulatory consultants, personnel related expenses, facility related expenses and laboratory supplies related to conducting research and development activities. Research and development expense was $37.7 million for the three months ended September 30, 2022, respectively, compared with $45.4 million in the comparable period last year, primarily reflecting decreased manufacturing costs of $10.9 million offset by an increase of $2.3 million in personnel related expenses and an increase of facilities expense of $0.7 million. Research and development expense was $120.8 million for the nine months ended September 30, 2022, respectively, compared with $141.1 million in the comparable period last year, primarily attributable to decreases in clinical and manufacturing costs of $27.3 million and lab supplies of $4.0 million, offset by increases in personnel costs of $7.7 million and facilities and equipment costs of $2.7 million and a decrease in contra research and development expenses $1.4 million. We expect that our research and development efforts and associated costs will increase and continue to be substantial over the next several years as our pipeline progresses.

Early stage programs represent programs that are in the pre-clinical or Phase 1 clinical stage and may be partnered or unpartnered, including the CF program. Discovery technologies represents our efforts to expand our product pipeline and are primarily related to pre-partnered studies and new capabilities assessment. For several of our programs, the activities are part of our collaborative and other relationships and the expenses may be partially offset with funds that have been awarded to the Company. The expenses primarily consist of external manufacturing costs, lab supplies, equipment, and consulting and professional fees. Both early stage programs and discovery technologies expenses are expected to steadily increase over the coming years.

Personnel related expenses primarily consist of employee salaries and benefits, share-based compensation and consultants and are expected to continue to increase in the near future as we continue increase headcount to meet the needs of our external pipeline, platform and clinical trial efforts. Additionally, personnel related expenses will continue to rise as we increase salaries in line with increases in the market rates in order to retain our employees.

Facilities and equipment expenses continue to increase as we expand. The nine months ended September 30, 2022 includes increased rent and associated costs related to a new facility we took possession of in April 2022. Facilities and equipment expenses are expected to increase in the near term due to increased rent expense related to our new facility.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries and related benefits for our executive, administrative, legal and accounting functions and professional service fees for legal and accounting services as well as other general and administrative expenses. General and administrative expense was $12.5 million and $34.2 million for the three and nine months ended September 30, 2022, respectively, compared with $10.9 million and $30.6 million in the comparable periods last year. The increases resulted primarily from personnel expense due to increased headcount and salaries, as well as increased rent expense associated with the new facility.

Finance (expense) income, net

(in thousands)	Three Months Ended September 30, 2022	2021	2021 to 2022 $ change	2021 to 2022 % change	Nine Months Ended September 30, 2022	2021	2021 to 2022 $ change	2021 to 2022 % change
Interest income	$ 444	$ 192	$ 252	131.3%	$ 766	$ 569	$ 197	34.6%
Interest expense	(765)	(711)	(54)	7.6%	(2,211)	(1,966)	(245)	12.5%
Total	$ (321)	$ (519)	$ 198	-38.2%	$ (1,445)	$ (1,397)	$ (48)	3.4%

Interest income is generated on cash and cash equivalents. The increases in interest income for the three and nine months ended September 30, 2022 as compared to the prior year periods were primarily a result of increased interest rates. Interest expense was incurred in conjunction with our Loan and Security Agreement with Western Alliance Bank and the Singapore Loan and was relatively flat for the three and nine months ended September 30, 2022 as compared to the prior year periods.

Other income and expense

(in thousands)	Three Months Ended September 30, 2022	2021	2021 to 2022 $ change	2021 to 2022 % change	Nine Months Ended September 30, 2022	2021	2021 to 2022 $ change	2021 to 2022 % change
Gain (loss) from equity-method investment	$ —	$ (250)	$ 250	-100.0%	$ (515)	$ 670	$ (1,185)	*
Gain from foreign currency	1,862	506	1,356	*	3,237	923	2,314	*
Total	$ 1,862	$ 256	$ 1,606	*	$ 2,722	$ 1,593	$ 1,129	70.9%

* *Greater than 100%*

Other income and expense items relate to gains and losses from foreign currency transactions and from equity-method investments. We recorded foreign currency gains of $1.9 million and $3.2 million for the three and nine months ended September 30, 2022, respectively, compared with gains of $0.5 million and $0.9 million in the comparable periods last year which is primarily attributable to the Singapore Loan.

We recorded no gain or loss for the three months ended September 30, 2022 and a loss of $0.5 million for the nine months ended September 30, 2022, compared with a $0.3 million loss and $0.7 million gain in the comparable periods last year in connection with our equity-method investment in Vallon Pharmaceuticals, Inc.

Off-balance sheet arrangements

Through September 30, 2022, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Liquidity and Capital Resources

From the Company’s inception through the quarter ended September 30, 2022, the Company has funded its operations principally with the proceeds from the sale of capital stock, long-term debt and revenues earned through collaboration agreements. At September 30, 2022, we had $237.7 million in unrestricted cash and cash equivalents.

During fiscal year 2021, the Company received a term loan of $46.6 million from Economic Development Board of the Republic of Singapore ("EDB"). The Company is in discussions with EDB regarding the loan and is expecting that it will pay back approximately $15.7 million during the first quarter of 2023, representing funds that were not spent on the original ARCT-021 COVID-19 vaccine candidate. The Company has notified EDB that the ARCT-021 program will not continue and has asked that the remaining portion of the loan related to the ARCT-021 program be forgiven at time the amendment is signed, which is expected during the fourth quarter of 2022.

Additionally, during 2021, the Company received an upfront payment of $40.0 million from Vinbiocare to fund the technology transfer and build out of a mRNA drug product manufacturing facility in Vietnam during 2021, in connection with entering into the Technology License and Technical Support Agreement and the Framework Drug Substance Supply Agreement, each signed July 29, 2021 and effective July 30, 2021 (collectively, the “License & Supply Agreements”). In October 2022, in association with the termination of the existing License and Supply Agreements, Vinbiocare and the Company signed a new Study Support Agreement which will fund certain parts of the Vietnam clinical trial. As such, the Company has reserved a portion of the original $40.0 million upfront payment within accrued expenses that will be paid over the next two years to Vinbiocare as part of the new Study Support Agreement.

Loan and Security Agreement

On October 12, 2018, we entered into a Loan and Security Agreement with Western Alliance Bank (the "Loan Agreement"). Pursuant to the Third Amendment, the Bank agreed to increase the Loan Agreement to $15.0 million on October 30, 2019. The Loan Agreement bears interest at a floating rate ranging from 1.25% to 2.75% above the prime rate. The amendment further provides that the Loan Agreement has a maturity date of October 30, 2023. The interest-only period ended on August 1, 2022,ad and we began making payments towards the principal balance.

Manufacturing Support Agreement

On November 7, 2020, our wholly-owned subsidiary, Arcturus Therapeutics, Inc., entered into a Manufacturing Support Agreement (the "Support Agreement") with the Economic Development Board of the Republic of Singapore (the "EDB"). Pursuant to the Support Agreement, the EDB agreed to make a term loan (the "Singapore Loan") of S$62.1 million to the Company, subject to the satisfaction of customary deliveries, to support the manufacture of the LUNAR-COV19 vaccine candidate (ARCT-021). The Singapore Loan accrues interest at a rate of 4.5% per annum calculated on a daily basis. We elected to borrow the full amount available under the Support Agreement of S$62.1 million ($46.6 million) on January 29, 2021. The EDB agreed to an extension of the reconciliation period to March 31, 2022, with unused funds as of such date returned to the EDB within 30 days following the completion of the customary audit of the Singapore Loan. This audit is scheduled to be completed during the fourth quarter of 2022. During the third quarter of 2022, we reported a portion of the Singapore Loan as current to reflect a potential principal repayment of approximately S$20.9 million ($15.7 million) in fiscal year 2022 based on amounts not used towards the manufacture of ARCT-021. We expect to refund this portion in the first quarter of fiscal year 2023.

The Singapore Loan was initially recorded as long-term debt at $46.6 million, the amount of cash proceeds at the time we received the funding. During the first quarter of 2022, accrued interest of $1.9 million related to 2021 was added to the principal debt balance in accordance with the terms of the Support Agreement and the balance was adjusted to reflect the current exchange rate resulting in an increase in the debt balance to $47.8 million. We recorded a net foreign currency transaction gain of $3.0 million for the nine months ended September 30, 2022 compared to a net foreign currency transaction gain of $0.9 million for the nine months ended September 30, 2021. For the three and nine months ended September 30, 2022, we recorded interest expense and a corresponding liability of $0.5 million and $1.6 million, respectively, compared to interest expense and a corresponding liability of $0.5 million and $1.4 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2022, we were in compliance with all covenants under the Singapore Loan and related commitments.

Vinbiocare Agreement

During 2021 we entered into the Technology License and Technical Support Agreement and the Framework Drug Substance Supply Agreement with Vinbiocare, a member of Vingroup Joint Stock Company (collectively, the "License & Supply Agreements"), whereby we would provide technical expertise and support services to Vinbiocare to assist in the build out of a mRNA drug product manufacturing facility in Vietnam. We received an upfront payment in aggregate of $40.0 million as part of the License and Supply Agreements. In October 2022, in association with the termination of the License and Supply Agreements, we signed the Study Support Agreement with Vinbiocare which continues Vinbiocare's clinical obligations and reserved a portion of the original $40 million upfront payment received from the License and Supply Agreements to be paid over the future periods.

The Study Support Agreement requires us to pay to Vinbiocare certain limited payments, including upon the occurrence of specified events through the first quarter of 2025. Vinbiocare is also eligible to receive a single digit percentage of amounts received by Arcturus on net sales, if any, of ARCT-154 (or next-generation COVID vaccine) up to a capped amount.

We have reclassified a portion of the $40 million upfront payment received from Vinbiocare under the License and Supply Agreements from deferred revenue to short-term and long-term liabilities, based on the anticipated timing of the payments to Vinbiocare by the Company under the Study Support Agreement, and removed that portion from the transaction price of the License and Supply Agreements. In association with the termination of the License and Supply Agreements, we have concluded that the Company has no remaining performance obligations as of September 30, 2022 related to the License and Supply Agreements, and therefore has recognized the remaining transaction price of $4.2 million as revenue during the period ended September 30, 2022. The revenue recognized in 2022 relates to the delivery of drug substance, consulting to support the build out of the manufacturing facility and technical transfer and consulting to support the phase 3 clinical trial.

General Financial Resources

We have a current unrestricted cash and cash equivalents balance of $237.7 million. On November 1, 2022, the Company entered into a collaboration and license agreement with CSL Seqirus and will receive an upfront payment of $200 million and will be eligible to potentially receive development milestones totaling more than $1.3 billion if all products are registered in licensed fields. We will also be entitled to potentially receive up to $3 billion in commercial milestones based on "net sales" of vaccines in the various fields. In addition, we are entitled to receive a 40% share of net profits from COVID-19 vaccine sales and up to low double digit

royalties of annual net sales for vaccines against influenza and the other three specified infectious disease pathogens, as well as royalties on revenues from vaccines that may be developed for pandemic preparedness. We expect to utilize our remaining funds on (i) the continued Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (ii) advances to our LUNAR-CF program toward submission of a CTA during the fourth quarter of 2022 and (iii) continued expansion of our platform and other general administrative activities.

Our future capital requirements are difficult to forecast and will depend on many factors that are out of our control. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. There can be no assurance that we will be able to obtain additional needed financing on acceptable terms or at all. Additionally, equity or debt financings may have a dilutive effect on the holdings of our existing shareholders.

We expect to continue to incur additional losses for the foreseeable future, and we will need to raise additional debt or equity financing or enter into additional partnerships to fund development. The ability of our Company to transition to profitability is dependent on identifying and developing successful mRNA drug candidates. If we are not able to achieve planned milestones, incur costs in excess of our forecasts, or do not meet covenant requirements of our debt, we will need to reduce discretionary spending, discontinue the development of some or all of our products, which will delay part of our development programs, all of which will have a material adverse effect on our ability to achieve our intended business objectives.

Funding Requirements

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin commercialization of our products. As a result, we will require additional capital to fund our operations in order to support our long-term plans. We believe that our current cash position will be sufficient to meet our anticipated cash requirements through at least the next twelve months, assuming, among other things, no significant unforeseen expenses, continued funding from partners at anticipated levels and our payment obligations continuing to follow the current maturity schedule under our long-term credit facility referenced in Note 5. We intend to seek additional capital through equity and/or debt financings, collaborative or other funding arrangements with partners or through other sources of financing. Should we seek additional financing from outside sources, we may not be able to raise such financing on terms acceptable to us or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Our future funding requirements are difficult to forecast and will depend on many factors, including the following:

- the development of our LUNAR-COV19 and LUNAR-FLU vaccine candidates;
- the achievement of milestones under our strategic alliance agreements;
- maintaining and/or expanding our manufacturing network and capabilities;
- the terms and timing of any other strategic alliance, licensing and other arrangements that we may establish;
- the initiation, progress, timing and completion of preclinical studies and clinical trials for our product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the costs and timing of procuring clinical and commercial supplies of our product candidates;
- the costs and timing of establishing sales, marketing and distribution capabilities;
- the costs associated with legal proceedings;
- the extent to which we acquire or invest in businesses, products or technologies; and
- market disruptions, including significant volatility in the financial markets caused by the Russia/Ukraine conflict.

Critical Accounting Policies and Estimates

We prepare our condensed consolidated financial statements in conformity with GAAP. As such, we make certain estimates, judgments and assumptions that we believe are reasonable, based upon information available to us. These judgements involve making estimates about the effect of matters that are inherently uncertain and may significantly impact our reported results of operations and financial condition. We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2021.

There have been no material changes to our critical accounting policies and estimates from the information provided in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, included in the 2021 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk is interest income and expense sensitivity and foreign currency exchange rates. Interest income and expense sensitivity is affected by changes in the general level of interest rates in the United States. Foreign exchange market risks relate to the grants and loan from the Singapore Economic Development Board which is discussed in this Quarterly Report in "Notes to Condensed Consolidated Financial Statements, Note 1. Description of Business." When deemed appropriate, we may manage our exposure to foreign exchange market risks through the use of derivative financial instruments. We may utilize such derivative financial instruments for hedging or risk management purposes. Due to the nature of our cash and cash equivalents and our evaluation of the potential impact of foreign currency exchange rates, we believe that we are not currently subject to any material market risk exposure.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer, our principal financial officer and our principal accounting officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, management has concluded that as of September 30, 2022, the Company's disclosure controls and procedures were effective at the reasonable assurance level, and we believe the condensed consolidated financial statements included in this Form 10-Q for the quarterly periods ended September 30, 2022 fairly present, in all material respects, our financial position, results of operations, comprehensive loss, statements of stockholders' equity and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer, our principal financial officer and our principal accounting officer, conducted an evaluation of the internal control over financial reporting to determine whether any other changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer, principal financial officer and principal accounting officer concluded that there were no changes in our internal controls over financial reporting during the periods covered by this Quarterly Report on Form 10-Q that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business, including those related to governmental inquiries, intellectual property and commercial relationships. The subject matter of any such legal proceedings or claims are or will be highlight complex and subject to substantial uncertainties. The outcome of any such proceedings or claims, regardless of the merits, are and will be inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment.

Item 1A. Risk Factors.

Our business is subject to various risks, including those described in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which we strongly encourage you to review. Other than as set forth below, there have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Commission on March 1, 2022.

U.S. Government agencies have special contracting authority that gives them the ability to terminate and/or modify its contracts.

On August 31, 2022, the Company entered into a cost reimbursement contract (the "Contract") with the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services to support the development of a low-dose pandemic influenza candidate based on Arcturus' proprietary self-amplifying messenger RNA-based vaccine platform.

The Contract, as with most U.S. Government contracts, is subject to audit, and contains termination provisions allowing the government to terminate all or part of the contract at its sole discretion, which will subject us to additional risks. These risks include the ability of the U.S. Government unilaterally to:

- preclude us, either temporarily or for a set period of time, from receiving new contracts or extending our existing or future contracts based on violations or suspected violations of laws or regulations;
- terminate our contract, either for the convenience of the government (at the government's sole discretion, for example, if funds become unavailable or the government no longer wants the work) or for default (for failing to perform in accordance with the contract schedule and terms);
- revise the scope and value of our contract and/or revise the timing for work to be performed;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products, if and when developed;
- claim rights to intellectual property, including products, that may be developed under the contract; and
- add or remove the terms and conditions in our contract.

Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, settlement expenses, and profit on the work completed prior to termination. A contractor's rights under a termination for convenience are limited to an adjustment of profit and, with the contracting officer's concurrence, a reduction in the estimated cost. Under the general termination for convenience procedures, a partial termination is treated as a full termination when (i) the terminated portion is clearly severable from the balance of the contract or (ii) when contract performance is virtually complete or performance of the continued portion of the contract is only on subsidiary items or is otherwise not substantial. Termination-for-default provisions do not permit these recoveries and could make us liable for excess costs incurred by the U.S. Government in procuring undelivered items from another source.

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

Several U.S. Government agencies, such as the Defense Contract Audit Agency (the "DCAA"), routinely audit and investigate government contractors. These agencies review, among other things, a contractor's performance under its contracts, incurred costs, cost structure and compliance with applicable laws, regulations and standards.

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

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

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

Effectiveness of our commercial arrangement with CSL Seqirus remains subject to regulatory approval, and failure to timely obtain such approval could negatively affect our future business and financial results.

Effectiveness of the Collaboration and License Agreement with CSL Seqirus is conditioned on the expiration of the waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976 ("HSR"). There is no assurance that we will receive the necessary HSR approval, and if HSR approval is not obtained, the Collaboration and License Agreement will terminate in accordance with its terms. Such termination could materially adversely affect our business, financial results, financial condition, and stock price.

Data from our ongoing Phase 1/2/3 clinical trials of ARCT-154 in Vietnam may not provide sufficient evidence to the Vietnamese regulatory authorities, the US FDA or regulatory authorities in other jurisdictions that it is sufficiently safe and effective to achieve any marketing approval (including any emergency use authorization) or to have a plausible clinical path to an approval.

The completion of these clinical trials in Vietnam and their review by Vietnamese regulatory authorities may be delayed substantially because of a recently exposed scandal involving COVID-19 testing kits. The scandal has resulted in expulsions of high-level officials in the Ministry of Health as well as Center for Disease Control directors & health officials in 14 provinces. Clinical trial results are inherently uncertain, and a significant portion of our potential success and business prospects currently depend on our COVID-19 vaccine program. If we cannot demonstrate sufficient safety and efficacy and complete these clinical trials on a timely basis, we likely will have missed a substantial market opportunity for COVID-19 vaccines, after dedicating significant efforts and financial resources to this program, and our commercial relationships may be materially adversely affected. Data from this trial is crucial for the success of the COVID-19 vaccine program.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Description
3.1	Certificate of Incorporation. Incorporated by reference to Annex B to the proxy statement/prospectus which forms part of the Registration Statement on Form S-4 filed on March 18, 2019 (File No. 333-230353).
3.2	Certificate of Amendment, dated November 25, 2020. Incorporated by reference to Exhibit 3.1 to Form 8-K filed on November 25, 2020 (File No. 001-38942).
3.3	Bylaws of Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3, filed with the SEC on May 8, 2020 (File No. 333-238139).
4.1	Description of Registrant's Securities. Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on February 28, 2022 (File No. 001-38942).
10.1†	Form of Indemnification Agreement. Incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).
10.2†	Amended and Restated 2019 Omnibus Equity Incentive Plan. Incorporated by reference Exhibit 4.3 to the Registration Statement on Form S-8 filed on August 5, 2020 (File No. 333-240397).
10.3**	Loan and Security Agreement, dated October 12, 2018, by and between Western Alliance Bank and Arcturus Therapeutics, Inc. Incorporated by reference to Exhibit 10.1 to the Company's Report of Foreign Private Issuer on Form 6-K filed on October 15, 2018 (File No. 001-35932).
10.4**	Amended and Restated Amendment to Development and Option Agreement, dated as of September 28, 2018, by and between CureVac AG and Arcturus Therapeutics Inc. Incorporated by reference to Exhibit 99.2 to the Company's Report of Foreign Private Issuer on Form 6-K filed on October 1, 2018 (File No. 001-35932).
10.5**	Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Janssen Pharmaceuticals, Inc., dated October 18, 2017. Incorporated by reference to Exhibit 4.7 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.6**	Research and Exclusive License Agreement, by and between Arcturus Therapeutics, Inc. and Synthetic Genomics, Inc., effective October 24, 2017. Incorporated by reference to Exhibit 4.8 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.7**	Research Agreement, by and between Arcturus Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, effective December 6, 2016, as amended December 21, 2017. Incorporated by reference to Exhibit 4.9 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.8**	Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Ultragenyx Pharmaceutical Inc., entered into as of October 26, 2015, as amended October 17, 2017 and April 20, 2018. Incorporated by reference to Exhibit 4.10 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.9**	Third Amendment to Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Ultragenyx Pharmaceutical Inc., effective June 18, 2019. Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 20, 2019 (File No. 001-38942).
10.10**	Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated May 16, 2017. Incorporated by reference to Exhibit 4.11 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.11**	Amendment No. 2 to Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated August 1, 2019. Incorporated by reference to Exhibit 10.16 to Form 10-Q filed on August 14, 2019.
10.12**	Development and Option Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated January 1, 2018, as amended May 3, 2018. Incorporated by reference to Exhibit 4.12 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.13**	Third Amendment to Development and Option Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated July 26, 2019. Incorporated by reference to Exhibit 10.20 to Form 10-Q filed on August 14, 2019 (File No. 001-38942).

10.14**	License Agreement, by and between Arcturus Therapeutics, Inc., as successor-in-interest to Marina Biotech, Inc., and Protiva Biotherapeutics Inc., dated as of November 28, 2012. Incorporated by reference to Exhibit 4.14 to Form 20-F/A filed on July 10, 2018 (File No. 001-35932).
10.15**	Patent Assignment and License Agreement, by and between Arcturus Therapeutics, Inc. and Marina Biotech, Inc., dated as of August 9, 2013. Incorporated by reference to Exhibit 4.15 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.16	Share Exchange Agreement, dated as of February 11, 2019, by and between Arcturus Therapeutics Ltd. and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 18, 2019 (File No. 001-35932).
10.17**	Amended and Restated Joint Venture, Research Collaboration and License Agreement, dated as of July 14, 2018 by and between Arcturus Therapeutics, Inc. and Providence Therapeutics, Inc. Incorporated by reference to Exhibit 10.14 to the Company's Amendment No. 1 to Annual Report on Form 10-K for the year ended December 31, 2018 filed on April 10, 2019 (File No. 001-35932).
10.18**	Research Collaboration Agreement, dated as of March 8, 2019 by and between Arcturus Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited. Incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 18, 2019 (File No. 001-35932).
10.19	Lease Agreement, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated October 4, 2017. Incorporated by reference to Exhibit 4.6 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.20	First Amendment to Lease Agreement, by and between Arcturus Therapeutics Holdings Inc. and ARE-SD Region No. 44, LLC dated February 1, 2020. Incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).
10.21**	Acceptance Letter, dated March 4, 2020, by and between Arcturus Therapeutics Holdings Inc. and the Economic Development Board of Singapore. Incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).
10.22**	Supply Agreement, dated August 17, 2020, by and between Arcturus Therapeutics, Inc. and the Israeli Ministry of Health. Incorporated by reference to Exhibit 10.32 to Quarterly Report on Form 10-Q filed on November 9, 2020 (File No. 001-38942).
10.23**	Manufacturing Support Agreement, dated November 7, 2020, by and between Arcturus Therapeutics Holdings Inc. and the Economic Development Board of Singapore. Incorporated by reference to Exhibit 10.33 to Quarterly Report on Form 10-Q filed on November 9, 2020 (File No. 001-38942).
10.24	Fourth Amendment to Loan and Security Agreement, dated December 1, 2020, by and between Arcturus Therapeutics, Inc. and Western Alliance Bank. Incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 7, 2020 (File No. 001-38942).
10.25†	2020 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 4.3 to Form S-8 filed on August 5, 2020 (File No. 333-240392).
10.26	Second Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated November 13, 2020. Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2020 (File No. 001-38942).
10.27	Third Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated February 25, 2021. Incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2020 (File No. 001-38942).
10.28	Arcturus Therapeutics Holdings Inc. Severance Policy for Executives. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on April 26, 2021 (File No. 001-38942).
10.29	Technology License and Technical Support Agreement, signed July 29, 2021 and effective July 30, 2021, by and between Arcturus Therapeutics, Inc. and Vinbiocare Research and Manufacture Joint Stock Company. Incorporated by reference to Exhibit 10.32 to Quarterly Report on Form 10-Q filed on August 10, 2021 (File No. 001-38942).

10.30	Framework Drug Substance Supply Agreement, signed July 29, 2021 and effective July 30, 2021, by and between Arcturus Therapeutics, Inc. and Vinbiocare Research and Manufacture Joint Stock Company. Incorporated by reference to Exhibit 10.33 to Quarterly Report on Form 10-Q filed on August 10, 2021 (File No. 001-38942).
10.31	Fifth Amendment to Loan and Security Agreement, dated October 27, 2021, by and between Arcturus Therapeutics, Inc. and Western Alliance Bank. Incorporated by reference to Exhibit 10.34 to Form 10-Q filed on November 9, 2021 (File No. 001-38942).
10.32	Lease, by and between Arcturus Therapeutics, Inc. and TPSC IX, LLC, dated September 29, 2021. Incorporated by reference to Exhibit 10.35 to Form 10-Q filed on November 9, 2021 (File No. 001-38942).
10.33†	Arcturus Therapeutics Holdings Inc. 2021 Inducement Equity Incentive Plan. Incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 filed on October 20, 2021 (File No. 333-260391).
10.34	Sixth Amendment to Loan and Security Agreement, dated April 19, 2022, by and between Arcturus Therapeutics, Inc. and Western Alliance Bank. Incorporated by reference to Exhibit 10.36 to Form 10-Q filed on May 8, 2022 (File No. 001-38942).
10.35†	Amended and Restated 2019 Omnibus Equity Incentive Plan, as amended. Incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed on June 30, 2022.
10.36* **	Cost Reimbursement Contract dated August 31, 2022, by and between Arcturus Therapeutics Holdings Inc. and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services.
10.37**	Study Support Agreement, dated October 31, 2022, by and between Arcturus Therapeutics, Inc. and Vinbiocare Research and Manufacture Joint Stock Company. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on November 4, 2022 (File No. 001-38942).
10.38* **	Collaboration and License Agreement, dated November 1, 2022, by and between Arcturus Therapeutics Holdings Inc. and CSL Limited.
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification by Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial statements and footnotes from the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 formatted in Inline Extensible Business Reporting Language (Inline XBRL): 101.INS Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document 101.SCH Inline XBRL Taxonomy Extension Schema 101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase 101.DEF Inline XBRL Taxonomy Extension Definition Linkbase 101.LAB Inline XBRL Taxonomy Extension Label Linkbase 101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Certain confidential portions of this exhibit have been redacted from the publicly filed document because such portions are (i) not material and (ii) would be competitively harmful of publicly disclosed.

† Management compensatory plan, contract or arrangement.

SIGNATURE

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.

ARCTURUS THERAPEUTICS HOLDINGS INC.

Date: November 9, 2022

By: /s/ Andy Sassine
Andy Sassine
Chief Financial Officer

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE 4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50122C00007	See Block 20C OS296560

5. ISSUED BY	CODE	ASPR-BARDA	6. ADMINISTERED BY *(If other than Item 5)*	CODE
ASPR-BARDA 200 Independence Ave., S.W.				

[***]

17. X CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*	18. SEALED-BID AWARD (*Contractor is not required to sign this document.)* Your bid on Solicitation Number , including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)
19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER LA VIVIAN R. PEASANT

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
ARCTURUS THERAPEUTICS INC 1605099 BY [***] *(Signature of person authorized to sign)*		BY *(Signature of the Contracting Officer)*	

AWARD/CONTRACT
1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)
RATING
PAGE OF PAGES
1
~~89~~
50AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

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

NAME OF OFFEROR OR CONTRACTOR

ARCTURUS THERAPEUTICS INC 1605099

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 46-1981974 DUNS Number: 078807357 Appr. Yr.: 2022 CAN: 1992131 Object Class: 25103 Period of Performance: 09/01/2022 to 08/31/2025				
1	CLIN 0001 Phase I Pilot Studies Obligated Amount: $63,239,785.00				63,239,785.00

SECTION B – SUPPLIES/SERVICES AND COST/PRICE

B.1 Brief Description of Supplies/Services

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) requires conduct of development activities for a pandemic influenza vaccine (pandFLU). The project will entail developing a vaccine against pandemic HxNx influenza based on the Contractor's platform technology, LUNAR® lipid nanoparticles (LNPs) and self-transcribing and replicating RNA (STARR™), used in the Contractor's COVID-19 vaccines, ARCT-021, currently in phase II clinical trials, ARCT-154, currently in a Phase I/II/III study in Vietnam, and ARCT-165, which is currently in Phase I studies along with ARCT- 154, as a booster vaccine targeting SARS-CoV-2 variants of concern (VOCs). The scope of work for this contract includes pandFLU preclinical and clinical development activities in the following areas: non- clinical efficacy studies; clinical activities and associated drug product manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities. In addition to the development work to be performed on a pandemic vaccine, one preclinical study on a quadrivalent seasonal influenza vaccine will be conducted.

B.2 Estimated Cost

This contract contains the cost provisions agreed upon by the Government and the Contractor.

B.2.1 Contract Budget Ceiling

The contract has a cost ceiling that the Contractor exceeds at its own risk. The contractor is responsible for managing its performance in accordance with the final scope of work and costs/prices incorporated into the contract. The government is not obligated to reimburse the Contractor for costs incurred in excess of the contract ceiling of $63,239,785

B.2.2. Contract Periods

This Contract consists of a base period for Pre-clinical and clinical development through Phase I clinical trials for pandFLU, and the performance of the single preclinical study with respect to qsFLU development that is specified in the Statement of Work.

B.3 Contract Line Item Numbers (CLINs) Schedule

This is a Cost Reimbursement contract.

B.3.1 Period of Performance

The period of performance (POP) includes Preclinical and Phase 1 studies.

CLIN	Period of Performance	Supplies/Services	Estimated USG Costs

BASE 0001	01 Sep 2022 to 31 Aug 2025 (36 months)	Pre-clinical and clinical development through Phase I clinical trials for pandFlu and one pre-clinical task concerning qsFLU	$63,239,785

B.3.2 Total Contract Value

The total potential value of this contract is $63,239,785.

B.4 Advanced Understandings

This Contract contains advanced understandings between the Government and the Contractor. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the costs, will be included in this Section if the Contracting Officer has granted approval prior to contract award.

B.4.1 – Rights of Refusal

The Government's rights to data first developed in the performance of this Contract, the Government's limited rights to preexisting data used during the development effort under this Contract and the Government's rights to use Subject Inventions developed under this Contract shall survive any transfer of such title to a Subject Invention any third party. The Government may either exercise or waive this first right of refusal in writing. submitted to the Contractor within ninety (90) calendar days of the initial notification to the Government of the Contractor's intent to conduct any such transfer of title to a Subject Invention. This Article shall not apply to transfers of title to technology created with the use of funding obtained outside of this Contract.

This Contract does not include the purchase of pandemic influenza vaccine (pandFLU). Contractor shall negotiate with the Government in good faith for fair and reasonable pricing for vaccine applied to the HD-MAPs that accounts for the Government's providing funds on this cost reimbursement contract. At this time, the government is not negotiating any type of follow-on contract.

B.4.2 Earned Value Management (EVM) Lite Requirements

Contractor's Program Manager (PM) will use the Statement of Work, a Work Breakdown Structure (WBS) with task descriptions, the Integrated Master Schedule (IMS), and project team meetings as the primary tools for scope, budget and schedule integration. The WBS serves as the fundamental building block for the IMS and financial reporting. The IMS maps-out the start and end dates for the total program and further breaks down the timeline by individual line items, tasks and sub-tasks. This will include monitoring contract-mandated ceilings to ensure on-time and on-budget completion of all programmatic deliverables. The PM will track the program status against this IMS on a monthly basis. The PM will determine if tasks are behind or ahead of schedule. Program timelines will be reported to BARDA in the monthly and quarterly
reports. When program tasks or subtasks are behind schedule (or threaten to be behind schedule)

the Program Team will meet to determine:

- The root cause of the delay;
- The successor tasks that may be impacted and the impact the global program timelines and budget;
- Potential actions to bring the task or subtask back within the necessary timelines; and
- The impact of these actions on the program (cost, schedule, and resource reallocation, etc.)

If program changes are required, the PI/PM will present the action plan and work with BARDA to implement any necessary changes to the project plan.

B.4.3 Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage

The Federal Government may not use, or authorize the use of, any products or materials provided under either this Contract or any future purchase from Contractor's domestic manufacturing capacity unless such use occurs in the United States and is protected from liability under a declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

B.4.4 Provisions to Applicable Costs

This section prohibits or restricts the use of contract funds which includes the following items (costs unallowable unless otherwise approved by the Contracting Officer):

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

b. Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value;

c. Accountable Government Property (as defined by HHS Government property policies;

d. Overtime;

e. General scientific meetings/conferences;

f. Travel costs including foreign travel;

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

h. Costs to be paid for the performance of a fixed-price subcontract that exceeds [***] of the total estimated cost of the Contract, whichever value is greater (for equipment purchases, [***] per unit);

i. Refreshments and Meal Expenditures;

j. Promotional Items Printing;

k. Payment of regulatory submission fees to the FDA or other U.S. regulatory agency;

l. BLA licensing or renewal fees;

m. Pre-contract costs.

B.4.5 Contracting Officer's Authorization (COA) for Subcontracting

The Contractor shall submit a Contracting Officer's Authorization (COA) approval request, to the Contracting Officer, for all subcontractors, consultants and equipment purchases proposed during the course of this contract. COAs for subcontractors and consultant agreements shall be submitting when the potential subcontract is expected to exceed [***] of total contract value, whichever is greater; for equipment purchases, when the unit price per item is expected to exceed [***]. The CO shall act on such approval requests within 30 days. The supporting documents shall include, but not be limited to:

1. Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the subcontractor(s);
2. The subcontractor's qualifications/capabilities statement as they pertain to the activities included in the proposed subcontract;
3. The subcontractor's willingness to perform under the Contractor (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
4. A complete subcontractor cost proposal or quote, in similar format as the Contractor's cost proposal.

B.4.7 Facility, Equipment and Product Ownership

In the event the Government terminates this contract for other than default, all Contractor- acquired Government Furnished Property (GFP) [as defined by 52.245-1], to include process equipment, is to be assessed by a reputable third-party firm that specializes in assigning fair market value of biopharmaceutical materials, supplies and equipment for the resale market. The Government will use this fair market value assessment in settlement, around the disposition of the GFP.

Ownership and applicable usage rights of all materials/product (e.g. vaccines, validated lots) manufactured and/or acquired with Government funds, throughout the Contract's entire period of performance, shall be retained by the Government. The Contracting Officer will direct the Contractor on the disposition (i.e. storage, transfer, disposal, etc.) of all Contractor acquired/manufactured Government materials/product.

SECTION C – STATEMENT OF WORK

C.1. STATEMENT OF WORK

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

C.2 REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

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

b. For the purpose of Section C and F, the Contracting Officer's Representative is the authorized representative of the Contracting Officer.

SECTION **D- PACKAGING AND MARKING**

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email, as described in Section F.

All physical deliverables shall be preserved, packaged, and marked in accordance with normal commercial practices to meet the packaging requirements of the carrier, including that which is necessary to prevent deterioration and damages due to the hazard of shipping, handling, and storing. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

- **Federal Acquisition Regulation Clauses Incorporated by Reference**

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/

The following FAR clauses, pertinent to Section E, are hereby incorporated by reference:

- 52.246-9 Inspection of Research and Development Apr 1984

All work under this contract may be subject to inspection and final acceptance by the Contracting Officer or the duly authorized representative of the Government. The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this contract.

SECTION F - DELIVERABLES / PERFORMANCE

F.1 Federal Acquisition Regulation Clauses Incorporated by Reference

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/

The following FAR clause, pertinent to Section F, is hereby incorporated by reference:

- 52.242-15 Stop-Work Order, Alternate I (Apr 1984) Aug 1989

F.1.2 ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in Section B.3.1.

F.2 DELIVERABLES

Successful performance of the Contract shall be deemed to occur upon completion of performance of the work set forth in Section C of this contract and upon delivery and acceptance by the COR of each of the deliverables described in Section F.2.1 below.

All deliverables and reporting documents listed within this Section shall be delivered electronically to the CO, CS, and the COR unless otherwise specified by the CO.

CDRL#	Deliverable	Deliverable Description	Reporting procedures and Due Dates
01	**Meetings**		
01.1	Post Award Teleconference	[***]	[***]
01.2	Kickoff Meeting	[***]	[***]

		[***]	[***]
01.3	Every 2 weeks Teleconference (Bi-Weekly/Monthly Meetings)	[***]	[***]
01.4	Quarterly Meetings	[***]	[***]

		[***]	[***]
01.5	FDA Meetings	[***]	[***]
01.6	Weekly check-in with project staff for contract	[***] [***] [***]	[***] [***] [***]

02	**Technical Reporting**		
02.1 (Monthly) 02.2 (Annual)	Monthly & Annual Technical Progress Reports/Annual Meeting	[***]	[***]

		[***]	[***]
02.3	Draft and Final	A draft Final Technical Progress	•The Draft Technical Progress Report shall be submitted 75

(Draft) 02.4 (Final)	Technical Progress Report	[***]	[***]
		[***]	[***]

02.5 (Draft) 02.6 (Final)	Draft and Final Study Reports, Clinical and Non-Clinical	[***]	[***]
02.7	FDA Manufacturing Reports	[***]	[***]
02.8	Product Development Source Material and	[***]	[***]

	Manufacturing Report	[***]	[***]
02.9	Contractor Locations	[***]	[***]
02.10	Clinical Report during Active Enrollment Periods	[***]	[***]

		[***]	[***]
02.11	Study Protocols	[***]	[***]
02.12	Specimen Collection for Future Use	[***]	[***]

		[***]	[***]
02.13	Final Data Submission Package	[***]	[***]

		[***]	[***]
02.14	Supplemental Technical Documents, Raw Data, or Data Analysis	[***]	[***]
03	**Audits**		
03.1	BARDA Audit	[***]	[***]
03.2	FDA Audits	[***]	[***]

		[***]	[***]
03.3	QA Audits	[***]	[***]
03.4	Risk Management Plan (RMP)	[***]	[***]

		[***]	[***]
03.5	Integrated Master Schedule (IMS) - GANTT Chart	[***]	[***]
03.6	Deviation Notification and Mitigation Strategy	[***]	[***]
03.7	Incident Report	[***]	[***]

		[***]	[***]
03.8	Go/No-Go In-Process Review (IPR) or Decision Gate Presentation	[***]	[***]
04	**Advance R&D Products**		
04.1	Technical Documents	[***]	[***]

		reserve the right to request within the PoP a non- proprietary technical document for distribution within the Government.	
04.2	Animal Model or Other Technology Transfer Package	[***]	[***]
04.3	Raw Data or Data Analysis	[***]	[***]
04.4	Publications	[***]	[***]
05	**Regulatory Documents**		
05.1	FDA Correspondence	[***]	[***]

05.2	FDA Submissions	[***]	[***]
06	**Press Releases**	[***]	[***]
07	**Data Management Plan**	[***]	[***]

		[***]	[***]
08	**Manufacturing Campaign Reports**	[***]	[***]

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates
		[***]	[***]
01	Kickoff Meeting	[***]	[***]

02	Monthly Teleconference	[***]	[***]
03	Monthly Technical Progress Reports	[***]	[***]
04	Final Data Submission Package	[***]	[***]
05	Draft Final Report and Final Report	[***]	[***]

F.2.1 - Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Article F of this contract, and in the Statement of Work.

i. Monthly Progress Report

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

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") in Section F.2. The progress report shall conform to the requirements set forth in this Section F.2.1.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses. a. This section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. b. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor

did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

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

ii. Draft Final Report and Final Report

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

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

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

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

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

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

iii. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations

and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

iv. Other Technical Reports

1. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

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

2. Supplemental Technical Documents

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP’s), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a nonproprietary technical document for distribution solely within the Government. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people.

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 5 business days of receipt. All documents shall be duly marked as either “Draft” or “Final.”

ii. FDA Submissions

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

- When draft documents are submitted for BARDA review, BARDA will provide feedback to Contractor within 3 business days of receipt.
- When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA’s written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either “Draft” or “Final.” Contractor shall provide copies, or a written summary, of any FDA correspondence within 5 business days of correspondence.

F.3 SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

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.

SECTION G - CONTRACT ADMINISTRATION

G.1 Contracting Officer

The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this Contract.

The Contracting Officer is the only individual with authority to act as agent of the Government under this Contract, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract and/or (5) otherwise change any terms and conditions of this Contract.

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

La Vivian Peasant – (202) 868-9151
Contracting Officer
Division of Contracts Management & Acquisition (CMA)
Biomedical Advanced Research & Development Authority
(BARDA) Email: lavivian.peasant@hhs.gov

G.2 Contracting Officer’s Representative

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

Chuong Huynh– (202) 260-2177 **(COR)**
Lead Interdisciplinary Scientist
Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research & Development Authority (BARDA)
Email: choung.huynh@hhs.gov

G.3 Deliveries

Documents shall be delivered electronically via email to the Contracting Officer (CO) and the COR.

G.4. Key Personnel

Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar 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 (30) calendar-day 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 with respect to such key personnel's role in this contract, 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. The following individuals are determined to be key personnel:

[***]

G.5 Invoicing Instructions

Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP)

- All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).

- Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.

- The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
  - Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
  - The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

- If your company is already registered to use IPP, you will not be required to re-register.

- If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

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

- The contractor shall submit invoices under this contract once per month. For indefinite delivery vehicles, separate invoices must be submitted for each order.

- Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.

- Invoices must include the Dun & Bradstreet Number (DUNS) of the Contractor.

- Invoices that include time and materials or labor hours CLINS must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

- Invoices that include cost-reimbursement CLINs must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

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

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative,

Other Indirects)- show rate, base and total amount; Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;

- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.
- Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting.
- The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1.
- An electronic copy of the payment request shall be uploaded into the designated electronic filing platform and an e-mail notification of the upload will be provided to the CO and COR
- Invoices-Cost and Personnel Reporting, and Variances from the Negotiated Budget

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG. Nothing in this section discharges the contractor's responsibility to comply with any applicable FAR Parts 30 or 31 clauses relating to cost reimbursement subcontracts. In order to verify allowability, further breakdown of costs may be requested at the Government’s discretion. The Contractor shall subcontract with Firm Fixed Price Contracts to the maximum extent practicable.

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

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

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor’s invoices. Incomplete invoices may be suspended by the Contracting Officer if the Contractor’s claimed costs cannot be substantiated.

G.5 REIMBURSEMENT OF COST

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

a. All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.
b. All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.
c. All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.
d. Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

- Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class or business class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).
- Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
- Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).
- Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.6 Providing Accelerated Payment to Small Business Subcontractors, FAR 52.232-40 (Nov 2021)

(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, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial products or commercial services.

(End of clause)

G.7 Contract Communication/Correspondence

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

G.8 Negotiated Indirect Rates and Ceiling

1. Pending the establishment of final indirect cost rates, which shall be determined based on audit of actual costs as provided in Subpart 42.7 of the Federal Acquisition Regulation, the Contractor shall be reimbursed for allowable indirect costs at the agreed upon provisional billing rates. The Contractor's audited final indirect costs are allowable, to the extent that they do not lead the Contractor to exceed the total estimated costs for performance of the contract awarded, or the Ceiling Rates, established under this contract. The Contractor is also directed to the requirement to provide the Government with notice, that actual costs are expected to exceed the costs estimates, as required by 52.232-20(b). The contractor is responsible for tracking all costs during performance, including indirect costs, and providing all required notices.

2. Notwithstanding the provisions of FAR 42.704, ceilings are hereby established on indirect costs reimbursable under this contract. Therefore, the Government will not be obligated to pay any additional amounts if the final indirect cost rates developed by the cognizant audit activity based on actual allowable costs exceed the ceiling rates set forth above. In the event the final indirect cost rates are less than the above-established ceiling rates, the negotiated final rates shall be reduced to conform to the lower rates.

3. Any costs over and above the established cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.
4.

Rate Type	Rate Ceiling	Allocation Base
Fringe Benefits	[***]	Total Salaries
G&A	[***]	Total Direct Costs

5. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer within the 6-months period following the end of its fiscal years during the period of contract performance

G.9 Post-Award Evaluation of Contractor Performance

a. *Purpose*: In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).
b. *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer’s Representative and the Contracting Officer.
c. *Performance Evaluation Factors*: Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or

service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).

d. *Contractor Review*: A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.
e. *Resolving Disagreements between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.
f. *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.
g. *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.
h. *Retention Period*: The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 Access and Disposition of Data

Subject to the provisions of FAR 52.227-14 and 52.227-14 Alt. II, and Sections H.14 and H.18 of this Contract, the Government shall have physical and electronic access to all documentation and data first generated in the performance of this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Contractor commitments and responses.

H.2 HHSAR Clause 352.232-71 Electronic Submission of Payment Requests

(a) Definitions. As used in this clause—

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

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

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

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

(End of Clause)

H.3 Personnel Qualifications

The Contractor shall provide curriculum vitae (CV) for each individual identified as key personnel. The CV shall clearly describe the individual’s knowledge, work experiences, registrations, and certifications, and applicable experience. The CV shall include a summary describing the individual’s involvement in similar work.

H.4 No Personal Services or Inherently Governmental Function

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government’s rights in any way under the other provisions of this contract, including those related to the Government’s right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

H.5 Acknowledgement of Federal Funding – Publication and Publicity

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

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00180."

Press Releases: 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.

H.6 352.270-4b, Protection of Human Subjects (Dec 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (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.
b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. 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.
c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).
d. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part,

work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.7 HHSAR 352.270-5b, Care of Life Vertebrate Animals (Dec 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.
c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.
d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

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

(End of clause)

H.8 Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS

Policy). The PHS Policy can be accessed at:
http://grants1.nih.gov/grants/olaw/references/phspol.htm

H.9 Dissemination of False or Deliberately Misleading Information

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

H.10 ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

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

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

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

d. In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS 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.

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

H.11 Confidentiality of Information

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.12 Institutional Responsibility Regarding Investigator 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 BARDA contracts, or proposed for such funding, which may include, for example, collaborators or

consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgibin/textidx?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 G agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
    2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA funded research.
d. Require that each Investigator who is planning to participate in the BARDA funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent

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

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA funded research.
f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

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

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

with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

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

H.13 Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

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

H.14 Prohibition on Contractor Involvement with Terrorist Activities

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

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

1.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/

The following FAR clauses, pertinent to Section I, are hereby incorporated by reference:

FAR Clause	Title	Date

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

52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications	Nov 2021
52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	Oct 2009
52.215-23	Limitations on Pass-Through Charges	Jun 2020
52.216-7	Allowable Cost and Payment	Aug 2018
52.216-8	Fixed Fee	Jun 2011
52.219-8	Utilization of Small Business Concerns	Oct 2018
52.219-28	Post-Award Small Business Program Representation	Sep 2021
52.222-2	Payment for Overtime Premiums *[*$0.00]*	July 1990
52.222-3	Convict Labor	Jun 2003
52.222-19	Child Labor-Cooperation with Authorities and Remedies	Jun 2022
52.222-21	Prohibition of Segregated Facilities	Apr 2015
52.222-26	Equal Opportunity	Sept 2016
52.222-35	Equal Opportunity for Veterans	Jun 2020
52.222-36	Equal Opportunity for Workers with Disabilities	Jun 2020
52.222-37	Employment Reports on Veterans	Jun 2020
52.222-38	Compliance with Veterans' Employment Reporting Requirements	Feb 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Nov 2021
52.222-54	Employment Eligibility Verification	May 2022
52.223-6	Drug-Free Workplace	May 2001
52.223-18	Encouraging Contractor Policy to Ban Text Messaging While Driving	Jun 2020
52.224-1	Privacy Act Notification	April 1984
52.224-2	Privacy Act	April 1984
52.224-3	Privacy Training	Jan 2017
52.225-13	Restrictions on Certain Foreign Purchases	Feb 2021
52.225-25	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications	Jun 2020
52.227-1	Authorization and Consent, Alternate I(Apr 1984)	Jun 2020
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Jun 2020
52.227-11	Patent Rights-Ownership by the Contractor	May 2014
52.227-14	Rights in Data – General, Alternate II (Dec 2007)	May 2014
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.232-9	Limitation on Withholding of Payments	Apr 1984
52.232-17	Interest	May 2014
52.232-20	Limitation of Cost	Apr 1984
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment Alt I (Feb 2002)	Jan 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Nov 2021

52.233-1	Disputes	May 2014
52.233-3	Protest After Award, Alternate I (Jun 1985)	Aug 1996
52.233-4	Applicable Law for Breach of Contract Claim	Oct 2004
52.242-1	Notice of Intent to Disallow Costs	Apr 1984
52.242-3	Penalties for Unallowable Costs	Sep 2021
52.242-4	Certification of Final Indirect Costs	Jan 1997
52.242-13	Bankruptcy	Jul 1995
52.243-2	Changes—Cost-Reimbursement, Alternate V (Apr 1984)	Aug 1987
52.243-6	Change Order Accounting	Apr 1984
52.243-7	Notification of Changes	Jan 2017
52.244-2	Subcontracts, Alternate I (Jun 2020)	Jun 2020
52.244-5	Competition in Subcontracting	Dec 1996
52.244-6	Subcontracts for Commercial Products and Commercial Services	Jan 2022
52.245-1	Government Property	Sep 2021
52.245-9	Use and Charges	Apr 2012
52.246-25	Limitation of Liability—Services	Feb 1997
52.249-6	Termination (Cost-Reimbursement)	May 2004
52.249-14	Excusable Delays	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

I.2 Department of Health and Human Services Acquisition Regulation (HHSAR) Clauses

Full text of HHSAR clauses may be accessed electronically at this address: http://www.hhs.gov/grants/contracts/contract-policiesregulations/hhsar

HHSAR Clause	Title	Date
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Dec 2015
352.211-2	Conference Sponsorship Request and Conference Materials Disclaimer	Dec 2015
352.211-3	Paperwork Reduction Act	Dec 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Dec 2015
352.223-70	Safety and Health	Dec 2015
352.224-71	Confidential Information (§ (c)(2)(i): None)	Dec 2016
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Dec 2015
352.233-71	Litigation and Claims	Dec 2015
352.237-75	Key Personnel	Dec 2015
352.239-74	Electronic and Information Technology Accessibility	Dec 2015

352.270-5b	Care of Live Vertebrate Animals	Dec 2015
352.270-6	Restriction on Use of Human Subjects	Dec 2015
352.270-11	Protection of Human Subjects-Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required	Dec 2015
352.270-13	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research	Dec 2015

I.2 Additional Contract Clause HHSAR

I.2.1 Additional HHSAR in Full Text

FAR 52.227-14, Rights in Data – General (May 2014), Alternate II (December 2007)

As prescribed in FAR 27.409(b)(3), the following paragraph is inserted into (g)(3) of the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice

(Dec 2007) (a) These data are submitted with limited rights under Government Contract No. 75A50120C00180 and subcontracts. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

i. To BARDA support service contractors for the purpose of providing technical assistance to BARDA in evaluating Contractor performance and deliverables; or providing contract administration services to the Government.

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

(End of notice)

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS SECTION

J - LIST OF ATTACHMENTS

- Attachment 1: Statement of Work, dated 24 Aug 2022, 10 pages
- Attachment 2: Invoicing Instructions for Cost Reimbursement Contracts
- Attachment 3: Sample Invoice/Payment Request and Contract Financial Report
- Attachment 4: Financial Report of Individual Project/Contract
- Attachment 5: Instructions for Completing Financial Report of Individual Project/Contract
- Attachment 6: Inclusion Enrollment Report
- Attachment 7: Research Patient Care Costs
- Attachment 8: Report of Government Owned, Contractor Held Property
- Attachment 9: Disclosure of Lobbying Activities

Statement of Work BAA-18-SOL-00003, AOI #12
Arcturus Therapeutics (Arcturus) Self-Amplifying mRNA-Based Vaccine For Rapid Influenza Response
8/24/2022

Background

The current COVID-19 pandemic has exemplified the need for highly efficacious vaccines as a medical countermeasure for pandemic outbreaks and the means to produce those vaccines quickly. There have been four influenza pandemics in little more than the past century and preparing for the next influenza pandemic is critical. mRNA-based vaccines have recently demonstrated safe and effective prevention of pandemic viral infection. mRNA-based vaccines can be rapidly developed so that a 60-day time frame from sequence identification to initiation of clinical trials can be achieved. In addition, US-based manufacturing capacity for mRNA products must be expanded and sustained to facilitate the production of hundreds of millions of doses required to vaccinate the public.

[***]

Statement of Work

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

The overall objective of this contract is to advance the development of pandFLU as a vaccine for the prevention of pandemic influenza infection. The scope of work for this contract includes pandFLU preclinical and clinical development activities in the following areas: non-clinical efficacy studies; clinical activities and associated drug product manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities. The R&D effort for pandFLU will progress in specific stages that cover the base performance segment (I) to be labeled Contract Line Item Number

(CLIN) 0001 as specified in this contract. Arcturus will complete the specific tasks required in discrete work segments. The scope of work is detailed in Phase I: Pilot Studies, which are outlined below:

I. Pilot Studies

II. Non-Clinical Efficacy (small animal) and initial Clinical Safety Phase

III. Good Manufacturing Practice (GMP) Manufacturing Scale-up and Non-Clinical Efficacy

IV. Clinical and Pivotal Non-Clinical Studies Phase

The contractor shall provide the following as outlined below and in the contract deliverables list:

Program Management (WBS 1.1)

1.1.1 Arcturus shall provide for the following as outlined below and in the contract deliverables list (Article F.2):

1.1.2 The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities.

1.1.3 A Principal Investigator (PI) responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.

1.1.4 Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program management; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.

1.1.5 A BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer. May be the PI or Project Manager.

1.1.6 Administrative and legal staff to provide development of compliant subcontracts, consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.

1.1.7 Administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors.

1.1.8 Contract Review Meetings. 1.1.8.1 The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to, meeting of the Contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.

1.1.8.2 The Contractor shall participate in teleconferences every two weeks between the Contractor and subcontractors and BARDA to review technical progress. Teleconferences or additional face-to-face meetings shall be more frequent at the request of BARDA.

1.1.9 Integrated Master Schedule 1.1.9.1 Within 30 calendar days of the effective date of the contract, the Contractor shall submit a first draft of an updated Integrated Master Schedule in a format agreed upon by BARDA to the Project Officer and the Contracting Officer for review and comment. The Integrated Master Schedule shall be incorporated into the contract and will be used to monitor performance of the contract. Contractor shall include the key milestones and Go/No Go decision gates. The IMS for the period of performance will be accepted by BARDA at the PMBR.

1.1.10Integrated Master Plan 1.1.10.1 Work Breakdown Structure: The Contractor shall utilize a WBS template agreed upon by BARDA for reporting on the contact. The Contractor shall expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by BARDA as part of their Integrated Master Plan for contract reporting. The CWBS shall be discernable and consistent. BARDA may require Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

1.1.10.2GO/ NO-GO Decision Gates: The Integrated Master Plan outlines key milestones with “Go/No Go” decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions.

1.1.10.3Earned Value Management System Plan: Subject to the requirements under HHSAR Clause 352.234-4, the Contractor shall use principles of Earned Value Management System (EVMS) in the management of this contract.

Contractor’s Program Manager (PM) will use the Statement of Work, a Work Breakdown Structure (WBS) with task descriptions, the Integrated Master Schedule (IMS), and project team meetings as the primary tools for scope, budget and schedule integration. The WBS serves as the fundamental building block for the IMS and financial reporting. The IMS maps-out the start and end dates for the total program and further breaks down the timeline by individual line items, tasks and sub-tasks. This will include monitoring contract-mandated ceilings to ensure on-time and on-budget completion of all programmatic deliverables. The PM will track the program status against this IMS on a monthly basis. The PM will determine if tasks are behind or ahead of schedule. Program timelines will be reported to BARDA in the monthly and quarterly reports. When program tasks or subtasks are behind schedule (or threaten to be behind schedule) the Program Team will meet to determine:

- The root cause of the delay;
- The successor tasks that may be impacted and the impact the global program timelines and budget;
- Potential actions to bring the task or subtask back within the necessary timelines; and
- The impact of these actions on the program (cost, schedule, and resource reallocation, etc.)

If program changes are required, the PI/PM will present the action plan and work with BARDA to implement any necessary changes to the project plan.

1.1.11Decision Gate Reporting: On completion of a stage of the product development, as defined in the agreed upon Integrated Master Schedule and Integrated Master Plan, the Contractor shall prepare and

submit to the Project Officer and the Contracting Officer a Decision Gate Report that contains (i) sufficient detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No Go decision making; and (ii) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development

1.1.12Risk Management Plan: The Contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan should reference relevant WBS elements where appropriate. Updates to this plan shall be included every three months (quarterly) in the monthly Project Status Report.

1.1.13Performance Measurement Baseline Review (PMBR): The Contractor shall submit a plan for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

I. Jointly assess areas such as the Contractor’s planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks

II. Confirm the integrity of the Performance Measurement Baseline (PMB)

III. Foster the use of EVM as a means of communication

IV. Provide confidence in the validity of Contractor reporting

V. Identify risks associated with the PMB

VI. Present any revised PMBs for mutual agreement

VII.Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI-MGMT-81650 may be referenced as guidance in creation of the IMS (see http://www.acq.osd.mil/pm/).

VIII. Present the Risk Management Plan

1.1.14Deviation Request: During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor shall submit a Deviation Report. This report shall request a change in the agreed-upon IMS and timelines. This report shall include: (i) discussion of the justification/rationale for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

1.1.15Monthly and Annual Reports: The Contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the WBS, SOW, IMS, and EVM:

I. Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory;
II.Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
III. Updated IMS;
IV. Updated EVM Light;
V. Updated Risk Management Plan (Every 3 months);
VI. Three month rolling forecast of planned activities;
VII. Progress of regulatory submissions;
VIII. Estimated and actual expenses;

1.1.16Data Management: The Contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;
1.1.16.1 Provide for the statistical design and analysis of data resulting from the research;
1.1.16.2 Provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.

1.2 **Non-Clinical Toxicology (WBS 1.2)**

[***]

1.3 **Non-Clinical Studies (WBS 1.3)**

[***]

1.4 **Clinical studies (WBS 1.4)**

[***]

1.5 **Regulatory (WBS 1.5)**

[***]

1.6 **Chemistry Manufacturing Controls (CMC) (WBS 1.6)**

[***]

1.6.5 Controls Analytical/Validation

[***]

Objectives:

[***]

Deliverables:

[***]

6.1 Facilities, Equipment and Other Resources.

[***]

Contract WBS milestones/Deliverables and Technical Deliverables

[***]

ATTACHMENT #2

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

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

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

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

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

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

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

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

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

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

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

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

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

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

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

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request. Include numbering in format of year_month #.

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

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

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

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

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

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

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

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

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

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

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

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

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

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

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost see the HHS *Contractor's Guide for Control of Government Property (https://archive.org/details/contractorsguide00unit)* (e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

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

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

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

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

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

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

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

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

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

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

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

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

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

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

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

(u) **Grand Totals**

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

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

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

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

(a) Designated Billing Office Name and Address: ATTN: Contracting Officer U.S. Department of Health & Human Services Office of the Assistant Secretary for Preparedness and Response Biomedical Research and Development Authority Contract Management and Acquisition (CMA) O'Neill House Office Building Room Number: 21C06 Washington, DC 20515 (b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:** **DUNS or DUNS+4:**	(c) Invoice/Financing Request No.: (d) Date Invoice Prepared: (e) Contract No. and Order No. (if applicable): (f) Effective Date: (g) Total Estimated Cost of Contract/Order: (h) Total Fixed-Fee (if applicable): (i) Two-Way Match: (j) Office of Acquisitions: (k) Central Point of Distribution: Three-Way Match:

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

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

(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.
(Name of Official)
(Title)
* Attach details as specified in the contract

Attachment 4

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance with Accompanying Instructions.	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at End of Prior Period**	**Incurred Cost--Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Negotiated Contract Amount**	**Variance (Over or Under) (I - H)**
	Negotiate	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

Attachment 5

INSTRUCTIONS FOR COMPLETING

"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by the Government in monitoring the application of financial and personnel resources to the BARDA funded contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An electronic copy of the report(s) shall be sent to the contracting officer at the address shown in the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for a copy to be sent directly to the Contracting Officer's Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.
Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

Attachment 6

INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:	
Total Enrollment:	**Protocol Number:**
Contract Number:	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

Attachment 7 - Research Patient Care Costs

Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.

(c) Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payers or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:	**CONTRACT NUMBER:**
ADDRESS:	**REPORT DATE:**
ADDRESSl:	
ADDRESS2:	**FISCAL YEAR:**
CITY:	
STATE:	
ZIP:	

CLASSIFICATION	**BEGINNING OF PERIOD**		**ADJUSTMENTS**			**END OF PERIOD**	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST >=$25K							
PROPERTY UNDER CONST <$25K							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING >=$25K							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP >=$25K							
SPECIAL TEST EQUIP <$25K							
AGENCY PECULIAR >=$25K							
AGENCY PECULIAR <$25K							
MATERIAL >=$25K (CUMULATIVE}							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							

SIGNED BY:			
SIGNATURE		DATE SIGNED:	

NAME PRINTED		Ema l	
TITLE		TELEPHONE	

"55"$).&/5 #9

DISCLOSURE OF LOBBYING ACTIVITIES Approved by OMB

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352 0348-0046

(See reverse for public burden disclosure.)

1.Type of Federal Action:	2.Status of Federal Action:	3.Report Type:
a.contract b.grant c.cooperative agreement d.loan e.loan guarantee f.loan insurance	a.bid/offer/application b.initial award c.post-award	a.initial filing b.material change **For Material Change Only:** year quarter date of last report _ _

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:
Prime Subawardee Tier ____, *if known* : **Congressional District**, *if known* : 4c	 **Congressional District**, *if known* :
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable* : _
8. Federal Action Number, *if known* **:**	**9. Award Amount,** *if known* **:** $
10. a. Name and Address of Lobbying Registrant (*if individual, last name, first name, MI*):	**b. Individuals Performing Services** (*including address if different from No. 10a*) (*last name, first name, MI*):
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: ____ Title: _____ Telephone No.: _ Date:

Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employeeof any agency, a Member of Congress, an officer or employee of Congress, or an employeeof a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizationallevel below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

COLLABORATION AND LICENSE AGREEMENT

between

ARCTURUS THERAPEUTICS, INC.

and

SEQIRUS INC.

Dated as of November 1, 2022

TABLE OF CONTENTS

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "**Agreement**") is made and entered into on November 1, 2022 (the "**Execution Date**") by and between Arcturus Therapeutics, Inc., a Delaware corporation ("**Arcturus**"), and Seqirus Inc., a Delaware corporation ("**Seqirus**"). Arcturus and Seqirus are sometimes referred to herein individually as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, Arcturus Controls certain Intellectual Property rights with respect to the Arcturus Technology;

WHEREAS, Arcturus is a messenger RNA medicines company focused on the discovery, development and manufacturing of therapeutics for rare diseases and vaccines, with deep expertise in lipid-mediated delivery, design and optimization of RNA constructs and manufacturing of RNA drug substance and drug product;

WHEREAS, Seqirus is involved in the research, development, manufacture and commercialization of vaccines for use in the prevention or prophylaxis of infectious diseases;

WHEREAS, the Parties wish to collaborate to Research and Develop Vaccine Candidates and Vaccine Products utilizing Arcturus Technology or a combination of Arcturus Technology and Seqirus Technology for further Development and Commercialization by Seqirus;

WHEREAS, Arcturus wishes to grant, and Seqirus wishes to take, a license under the Arcturus Technology and related Intellectual Property rights to Research, Develop, Manufacture and Commercialize the Vaccine Candidates and Vaccine Products in the Fields in the Territory, in each case in accordance with the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. "**Acceptance**" means, with respect to a BLA or EUA, [***].

1.2. "**Accounting Standards**" means, (a) with respect to a Arcturus, that Arcturus shall maintain records and books of accounts in accordance with United States Generally Accepted Accounting Principles or (b) with respect to Seqirus, that Seqirus shall maintain records and books of accounts in accordance with Australian Accounting Standards as issued by the Australian Accounting Standards Board or (c) with respect to calculations by a Sublicensee, the Sublicensee

shall maintain records and books of account in accordance as utilized for its audited financial statements and if no audited financial statements are issued, then in accordance with United States Generally Accepted Accounting Principles. All changes in Accounting Standards required by the applicable governing body shall be recorded in the calculations in the year of such change.

1.3. "**Acquirer**" means, with respect to a Party, the Person that is a party to a Change of Control with such Party after the Execution Date.

1.4. "**Acquirer IP**" means, with respect to an Acquirer, [***] or (b) [***].

1.5. "**Acquirer Technology**" means, with respect to an Acquirer, all proprietary technology Controlled by such Acquirer (other than proprietary technology Controlled by Arcturus or by Affiliates that Arcturus directly or indirectly controls (as defined in the definition of Affiliate)).

1.6. "**Affiliate**" means, any entity that directly or indirectly controls or is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, "control" or "controlled" means ownership directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls, is controlled by, or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case, such lower percentage shall be substituted in the preceding sentence; provided, that such foreign investor has the power to direct or cause the direction of the management and policies of such entity. For the avoidance of doubt, an entity shall cease to be an "Affiliate" hereunder upon the date that such entity no longer satisfies the requirements set forth in this definition.

1.7. "**Agreement**" has the meaning set forth in the preamble hereto.

1.8. "**Alliance Manager**" has the meaning set forth in Section 2.2.5 (Alliance Manager).

1.9. "[***]" has the meaning set forth in Section 5.7.2 ([***]).

1.10. "**APA**" means an agreement, such as an advanced purchase agreement, entered into by Seqirus (or an Affiliate of Seqirus) with a governmental or non-governmental entity pertaining to the future purchase of, or reservation of manufacturing capacity for, a secure supply of [***].

1.11. "**APA Revenue**" means the gross amounts received by Seqirus under an APA.

1.12. "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, major national securities exchanges or major securities

listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.13. "[***]" has the meaning set forth in Section 5.6.1 [***].

1.14. "[***]" has the meaning set forth in Section 5.6.1 [***].

1.15. "**Arcturus**" has the meaning set forth in the preamble hereto.

1.16. "**Arcturus BARDA Agreement**" means the agreement dated as of August 31, 2022 by and between Arcturus and the US Biomedical Advanced Research and Development Authority ("**BARDA**").

1.17. "

1.18. "**Arcturus Delivery Technology**" has the meaning set forth in Schedule 1.30.

1.19. "**Arcturus Foreground IP**" means: (a) Foreground IP developed [***], in either case, that relates specifically to [***] (except [***]); and (b) [***]. References in this definition to subject matter that is developed by a Party include such subject matter developed by an Affiliate of such Party or a Third Party on behalf of such Party.

1.20. "**Arcturus Indemnitees**" has the meaning set forth in Section 11.1 (Indemnification of Arcturus).

1.21. "**Arcturus Know-How**" means any and all Know-How under the Arcturus Technology.

1.22. "**Arcturus Licensed IP**" means [***]; and any Intellectual Property which is Controlled by Arcturus during the Term concerning or related to Arcturus Technology (including any such Information or Intellectual Property collected or otherwise generated in the performance of Arcturus Ongoing Third-Party Obligations). Arcturus Licensed IP shall exclude [***].

1.23. "

1.24. "**Arcturus Ongoing Third-Party Obligations**" means Arcturus obligations under [***].

1.25. "**Arcturus Patent(s)**" means any and all Patents under the Arcturus Licensed IP, including the Patents listed on Schedule 10.2.1.

1.26. "[***]" means [***], which are identified using [***]internal naming processes including, "[***]".

1.27. "**Arcturus R&D Support**" has the meaning set forth in Section 3.3 (Arcturus R&D Support Period).

1.28. "**Arcturus R&D Support Period**" has the meaning set forth in Section 3.3 (Arcturus R&D Support Period).

1.29. "**Arcturus Research and Development Costs**" means [***].

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

1.31. "**Audit Arbitrator**" has the meaning set forth in Section 6.16 (Audit Dispute).

1.32. "**Background IP**" means, with respect to a Party, Intellectual Property which exists and is Controlled by such Party as of the Effective Date.

1.33. "**Bankruptcy Code**" has the meaning set forth in Section 12.8.1 (Applicability of 11 U.S.C. § 365(n)).

1.34. "**Biosimilar Product**" means, with respect to a particular [***] in a [***], a [***] that (a) contains an [***], (b) is [***] based on [***], whether or not such [***] was based in whole or in part upon [***] or [***], and (c) is so[***].

1.35. "[***]" means the [***] or [***] containing [***] or [***] and contemplated to be [***] under [***] as of the Effective Date. If the Parties determine to replace or transition [***] of such [***] with another [***], then, upon mutual written agreement of the Parties, the [***] shall be deemed to be such [***] or [***].

1.36. "**BLA**" has the meaning set forth in the definition of "Drug Approval Application".

1.37. "**Breaching Party**" has the meaning set forth in Section 12.2 (Termination for Material Breach).

1.38. "**Business Day**" means a day other than a Saturday or Sunday on which banking institutions in both New York, New York and Melbourne, Australia are open for business.

1.39. "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.40. "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.41. "**Centralized Approval Procedure**" means the procedure through which a MAA filed with the EMA results in a single marketing authorization valid throughout the European Union.

1.42. "**Change of Control**" means, with respect to a Party, (i) a merger or consolidation of such Party with a Person, which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation; (ii) the sale or other transfer of all or substantially all of such Party's assets to another Person; (iii) a transaction or a series of related transactions in which a Person, together with its Affiliates, becomes the owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party; or (iv) a change in a majority of the members of the board of directors of a Party (or, if applicable, the board of directors of a successor corporation of such Party) by means of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents of the owners of such Party's securities which has not been approved (prior to such transaction) by the then immediately prior members of the board of directors (or any other applicable governing body) of such Party.

1.43. "**Clinical Data**" means all Information with respect to any Vaccine Candidates or Vaccine Products and made, collected, or otherwise generated under or in connection with Clinical Studies, including any protocol, investigator's brochure, study approval documentation, statistical plans, data (including raw data), reports, and results with respect thereto.

1.44. "**Clinical Studies**" means Phase I Study, Phase II Study, Phase III Study, Phase IV Study, and such other tests and studies in human subjects including surveillance and real world studies that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, or necessary or useful, to obtain or maintain Regulatory Approval for a Vaccine Product for [***], including [***], [***] or [***] and [***] for [***].

1.45. "**CMC Data**" means the chemistry, manufacturing and controls data required by Applicable Law to be included in a Drug Approval Application for a Vaccine Product.

1.46. "**Collaboration Know-How**" means Know-How that is Foreground IP (other than Patents) and that is either (i) an update, modification, derivative or improvement of a the Know-How in a Party's Background IP or (ii) generated by either Party in the performance of Research or Development.

1.47. "**Combination Product**" means a Vaccine Product that is comprised of or contains [***] as an active ingredient together with (but not co-formulated with) [***] or other active ingredients and is [***]. For clarity, Combination Product includes a Combination Vaccine.

1.48. "**Combination Vaccine**" means a [***] (a) the [***], (b) the [***], (c) the [***], or (d) one or more of [***]. For these purposes, a [***] shall be considered [***]. For clarity, Combination Vaccine shall not, and is not intended to, expand the scope of the license grant to Seqirus to any field outside of the Fields, and any vaccine component that [***] and does not [***] will not be within the license granted by Arcturus and shall not make use of or incorporate [***] or [***].

1.49. "**Commercialization**" means any and all activities directed to the [***] for [***], [***], or [***] of [***], including activities related to [***], [***], [***], [***] and [***] such [***], and, for purposes of setting forth the rights and obligations of the Parties under this Agreement, shall be deemed to include conducting [***], and [***] with [***] regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.50. "**Commercially Reasonable Efforts**" means, with respect to the performance of the obligations at issue with respect to the activities undertaken by a Party under this Agreement, the carrying out of such activities using efforts and resources comparable to the efforts and resources that such Party (including for clarity, its Affiliates) would typically devote with respect to its own products of similar market potential at a similar stage in development or product life, taking into account all [***], [***], and [***], including [***], [***], [***] and [***] (including [***] and [***] hereunder or [***]), [***] and [***] of [***] (including [***]) in [***], the [***] of [***] and [***] ([***] and [***]), the [***] of [***], the [***] and [***] and [***], and the [***] and [***] of [***] and [***]. Commercially Reasonable Efforts will be [***] on a [***], as applicable, and it is anticipated that the [***] of [***] and [***] that constitute "Commercially Reasonable Efforts" with respect to [***], reflecting [***] in the [***] of [***] and [***], as applicable, the [***], and the other factors set forth in this Section 1.50 (Commercially Reasonable Efforts).

1.51. "**Competing Product**" means, with respect to [***], [***] or [***] of a particular [***] or [***] (including [***] of the [***] thereof) being [***] or [***] for the same [***] as a [***] or [***] use in such [***] (or, with respect to the [***], with such [***]).

1.52. "**Confidential Information**" means [***].

1.53. "**Contributed Background Know-How**" means, with respect to a Party, [***]

1.54. "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue or otherwise (other than by operation of the license and other grants in [***] or [***], to grant a license, sublicense or other right (including the right to reference [***]) to or under such [***], [***], [***], [***], or [***] or other arrangement with any Third Party; provided, however, that if (a) the grant to [***] of access to or a license under such item or right and/or (b) the exercise by [***] of rights under such license, as provided herein, in either case ((a) or (b)), would trigger [***] by [***] to [***], such item or right, as applicable, shall only be deemed to be [***] by [***] if [***] agrees to (i) [***], and (ii) [***].

1.55. "**Corporate Names**" means the Trademarks and logos identified on Schedule 1.55 and such other names and logos as the Parties may designate in writing from time to time.

1.56. "**Cost of Goods Sold**" means the reasonable, documented and verifiable cost of acquisition and/or manufacture of Vaccine Products incurred and recorded by the Selling Person or its Affiliates as prepared and calculated in each case to the extent specifically identifiable to the

Manufacture of such Vaccine Product in accordance with Australian Accounting Standards, other authoritative pronouncements of the Australian Accounting Standards Board, International Financial Reporting Standards (IFRS) and the Corporations Act 2001, and the costing methodology employed by the Selling Person, consistently applied (including consistency with calculation methodology utilized for externally reported financial statements): (i) [***], (ii) [***], (iii) [***] (i.e. [***]), (iv) [***], and (v) [***], including [***] and [***], plus (vi) [***] of [***] with [***] (including, but not limited to, [***]). For avoidance of doubt, any calculation of Cost of Goods Sold shall exclude [***] for the [***] and shall exclude any [***].

1.57. "**CREATE Act**" has the meaning set forth in Section 7.2.5 (CREATE Act).

1.58. "**Default Notice**" has the meaning set forth in Section 12.2 (Termination for Material Breach).

1.59. "**Design and Optimization**" means Research platform-based activities related to:

1.59.1. the following [***] activities for [***]: [***] methods and [***], [***] methodology, [***] and [***],

1.59.2. the following methodologies for the design and optimization of[***], and

1.59.3. the following methodologies related to [***].

1.60. "**Development**" means all activities [***]. When used as a verb, "**Develop**" means to engage in Development. For purposes of clarity, Development shall include [***].

1.61. " **Development Milestone Payment**" has the meaning set forth in Section 6.3 (Development Milestones).

1.62. "**Dispute**" has the meaning set forth in Section 13.6 (Dispute Resolution).

1.63. "**Distributor**" has the meaning set forth in Section 4.7 (Distributorships).

1.64. "**Dollars**" or "**$**" means United States Dollars.

1.65. "**Drug Approval Application**" means a New Drug Application or Biologics License Application (a "**BLA**") as these terms are defined in the FFDCA and section 351 of the Public Health Service Act (42 U.S.C. § 262), respectively, and the FDA rules and regulations implementing such statutes, or any corresponding foreign application, including, with respect to the European Union, a Marketing Authorization Application (a "**MAA**") filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure in the Territory, including all supplements of such applications.

1.66. "**Effective Date**" has the meaning set forth in Section 12.1.2 (Term).

1.67. "**EMA**" means the European Medicines Agency and any successor agency(ies) or authority having substantially the same function.

1.68. "**EUA**" means an authorization issued by the FDA under section 564 of the FFDCA (21 U.S.C. § 360bbb-3) or similar mechanisms in other jurisdictions whereby certain unapproved medical products are allowed to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biologic, chemical, or nuclear agents when there are no adequate, approved, and available alternatives. An EUA may also authorize unapproved uses of approved medical products in certain emergency circumstances.

1.69. "**European Union**" or "**EU**" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto.

1.70. "**Exchange Rate**" has the meaning set forth in Section 6.10 (Mode of Payment).

1.71. "**Excluded Targets**" has the meaning set forth in Section 5.9.1(ii).

1.72. "**Execution Date**" has the meaning set forth in the preamble hereto.

1.73. "**Existing Patents**" has the meaning set forth in Section 10.2.1 (Existing Patents).

1.74. " **Existing Regulatory Documentation**" means the Regulatory Documentation Controlled by Arcturus or any of its Affiliates as of the Effective Date.

1.75. "**Exploit**" or "**Exploitation**" means to [***], including [***], or [***].

1.76. "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.77. "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.78. " **Fields**" means the Influenza Field, SARS-CoV-2 Field, Pandemic Preparedness Field and Other Pathogens Field, as further described herein. "**Field**" shall mean any of the Fields.

1.79. "**Field Term**" has the meaning set forth in Section 12.1.2 (Term).

1.80. "**First Commercial Sale**" means, in respect of a product in a country, the earlier of (i) [***] or (ii) [***]. [***].

1.81. "**Foreground IP**" means the Intellectual Property rights arising under or subsisting in any discovery, improvement, invention (whether patentable or unpatentable), or

Information that arises in connection with each Party's activities (i) under any of the Plans, and any other activities related to the Research, Development or Manufacturing of Vaccine Candidates or Vaccine Products, or (ii) otherwise in the course of such Party's exercise of the licenses granted herein, in each case of (i) and (ii) during the Term.

1.82. "[***]" means [***] that specifically relates to [***].

1.83. "**FTE**" means [***].

1.84. "**FTE Costs**" means, [***].

1.85. "**FTE Rate**" means [***] set forth in Schedule 1.85.

1.86. "**GCP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guideline adopted by the International Conference on Harmonization, titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality assurance guidelines promulgated under the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

1.87. "**GLP**" means the then-current good laboratory practices and procedures promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or comparable regulatory standards promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

1.88. " **GMP**" means the current good manufacturing practices applicable from time to time to the Manufacturing of a Vaccine Candidate or Vaccine Product or any intermediate thereof pursuant to Applicable Law.

1.89. "**Gross Profit**" means for [***] in [***] in [***], [***] of [***] in such [***] with respect to [***] of [***] in such [***].

1.90. "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

1.91. "**HSR Filing**" has the meaning set forth in Section 12.1.1 (HSR and Other Governmental Filings).

1.92. "**In-Licensed Agreements**" has the meaning set forth in Section 10.2.4.

1.93. "**In-Licensed Patents**" has the meaning set forth in Section 10.2.4.

1.94. " **IND**" means an application submitted to a Regulatory Authority requesting authorization to commence Clinical Studies, including (a) an Investigational New Drug Application as defined in 21 C.F.R. Part 312 or any successor application or procedure submitted

to the FDA, (b) any equivalent clinical trial application in other countries or regulatory jurisdictions, and (c) all supplements, amendments, variations, extensions and renewals thereof that may be submitted or requested with respect to the foregoing.

1.95. "**Indemnification Claim Notice**" has the meaning set forth in Section 11.3 (Notice of Claim).

1.96. "**Indemnified Party**" has the meaning set forth in Section 11.3 (Notice of Claim).

1.97. "**Indirect Taxes**" has the meaning set forth in Section 6.13.3.

1.98. "**Influenza Field**" means [***].

1.99. "**Information**" means all knowledge of a technical, scientific, business and other nature, including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Regulatory Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents (e.g., plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

1.100. "**Initiation**" means, with respect to a Clinical Study, the first dosing of the first human subject in such Clinical Study.

1.101. "**Intellectual Property**" means any Patent, copyright, Trademark, trade name, service mark, service name, brand mark, brand name, logo, corporate name, or industrial design, any registrations thereof and pending applications therefor (to the extent applicable), any other Intellectual Property right (including, without limitation, any Know-How, trade secret, trade right, formula, conditional or proprietary report or information) relating to any of the foregoing.

1.102. "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 2.1.1 (Formation).

1.103. "**Know-How**" means any proprietary chemical or biological materials and other tangible materials or intangible information, including data, inventions (including, for clarity, inventions), practices, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, assays, skills, techniques, information required for governmental or regulatory submissions (including all regulatory materials submitted or required to be submitted to a Regulatory Authority, or received from a Regulatory Authority, in connection with a clinical trial, manufacturing or marketing authorization), and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical data and analytical and quality control data, patentable or otherwise.

1.104. "**Knowledge**" means the actual knowledge, after reasonable inquiry, of [***].

1.105. " **Large Scale Manufacturing**" means GMP Manufacturing for late-stage Development and Commercialization purposes.

1.106. "**Lead Candidate**" has the meaning set forth in Section 5.7.3 (Seqirus Restrictions in Fields).

1.107. "**Lien**" has the meaning set forth in Section 10.4.4.

1.108. "**Losses**" has the meaning set forth in Section 11.1 (Indemnification of Arcturus).

1.109. "**Lot to Lot Consistency Study**" means a clinical study undertaken to demonstrate equivalent safety and efficacy (or immunogenicity if agreed by the applicable Regulatory Authority) comparing the same Vaccine Candidates or Vaccine Products from different manufacturing batches, as set forth in the SARS-CoV-2 Development Plan.

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

1.111. "**MAA**" has the meaning set forth in the definition of Drug Approval Application.

1.112. "**Major Market**" means the [***].

1.113. " **Manufacture**" and "**Manufacturing**" means all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labelling, shipping, and storage holding of the Vaccine Candidates, any Vaccine Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.114. "**Manufacturing Process**" has the meaning set forth in Section 4.10 (Manufacturing Technology Transfer Upon Seqirus' Request).

1.115. "**Manufacturing Technology Transfer**" has the meaning set forth in Section 4.10 (Manufacturing Technology Transfer Upon Seqirus' Request).

1.116. "**Medical Affairs Activities**" means, with respect to any country or other jurisdiction in the Territory, the coordination of medical information requests and field based medical scientific liaisons with respect to Vaccine Candidates or Vaccine Products, including activities of medical scientific liaisons and the provision of medical information services with respect to a Vaccine Candidate or Vaccine Product.

1.117. "[***]" has the meaning set forth in Section 5.6.3 ().

1.118. "[***]" has the meaning set forth in Section 5.6.3 ().

1.119. "**Monthly Average Exchange Rate**" has the meaning set forth in Section 6.10 (Mode of Payment).

1.120. "**Net Sales**" means, the [***] by Seqirus, its Affiliates and/or Sublicensees (which shall not include Distributors or wholesalers) as the case may be (each a "**Selling Person**") to third parties, less the following deductions, in each case to the extent specifically related to the Vaccine Product and taken by the Selling Person or otherwise paid for or accrued by the Selling Person ("**Permitted Deductions**"):

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***]; and

(g) [***].

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of the Selling Person, which must be in accordance with the applicable Accounting Standards.

For purposes of calculating Net Sales, all Net Sales shall be converted into Dollars in accordance with Section 6.10 (Mode of Payment).

If any [***] is sold as part of a [***], the portion of Net Sales from [***], for the [***] or [***], shall be [***] of the [***] during the applicable [***], by [***], where [***], and [***]. If such [***] amount [***] or [***] for both the [***] and all [***] in the [***], Net Sales for the purposes of determining [***] and [***] the [***] shall be [***] by the Parties in good faith negotiations based on [***].

1.121. "**Net Sales-Based Milestone Payment**" has the meaning set forth in Section 6.4 (Net Sales-Based Milestones).

1.122. "**Nomination**" means the written notification by Seqirus to Arcturus of the selection of a Vaccine Candidate under a Research Plan for the initiation of an IND-enabling toxicology study.

1.123. "**Non-Breaching Party**" has the meaning set forth in Section 12.2 (Termination for Material Breach).

1.124. "**Other Foreground IP**" has the meaning set forth in Section 7.1.2(v) (Other Foreground IP).

1.125. "**Other Pathogens Field**" means [***].

1.126. "**Owned Patents**" has the meaning set forth in Section 10.2.4.

1.127. "**Pandemic Preparedness Field**" or "**PP Field**" means [***].

1.128. "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.129. "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, revivals, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)), and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.130. "**Payment**" has the meaning set forth in Section 6.13.1

1.131. "**Payment Term**" means, with respect to each [***] and [***] or other [***] in [***] , the period beginning on [***] in [***] or [***], and ending on [***] to [***] (a) the [***] of the [***] of [***] in [***] or [***] (provided, that, with respect to a [***], the remaining time period provided in this clause (a) that would be applicable for the Vaccine Product underlying such [***] shall be extended by an additional [***]; provided, further, that [***] extension shall occur not more than [***] (i.e., [***], and [***]) regardless of the number of subsequent [***] per Vaccine Product), and (b) the [***], [***] or [***] of the [***] that [***] a [***] that [***] such [***] in such [***] or [***].

1.132. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.133. "**Phase I Study**" means a human clinical trial of a Vaccine Candidate or Vaccine Product conducted in any country that is designed or intended to establish a preliminary determination of safety, tolerability, pharmacological activity or pharmacokinetics of the Vaccine Candidate or Vaccine Product in healthy individuals or patients prescribed by the Regulatory Authorities, including studies that would satisfy the requirements of 21 C.F.R. §312.21(a), as amended, or its non-United States equivalents.

1.134. "**Phase II Study**" means a human clinical trial of a Vaccine Candidate or Vaccine Product conducted in any country, the principal purpose of which is to make a determination of initial safety and efficacy in the target patient population, and which is prospectively designed to generate sufficient data that may permit commencement of pivotal

clinical trials or a similar clinical study prescribed by the Regulatory Authorities, from time to time pursuant to Applicable Law or otherwise, including a study that would satisfy the requirements of 21 C.F.R. §312.21(b), as amended, or its non-United States equivalents.

1.135. "**Phase III Study**" means a human clinical trial of a Vaccine Candidate or Vaccine Product in an indicated patient population conducted in any country with a defined dose or a set of defined doses for the product that is designed to establish that a Vaccine Candidate or Vaccine Product is safe and efficacious for its intended use and to determine the benefit/risk relationship, warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support marketing approval of such Vaccine Candidate or Vaccine Product, and such study that would satisfy the requirements of 21 C.F.R. §312.21(c), as amended or its non-United States equivalents.

1.136. "**Phase III Modified Enhanced Vaccine Product**" has the meaning set forth in Section 1.195 ("Vaccine Product").

1.137. "**Phase IV Study**" means a clinical trial of a Vaccine Product that is commenced after receipt of Regulatory Approval and may include post-marketing surveillance trials, epidemiological studies, or modeling and pharmacoeconomic studies, among others, and may be initiated voluntarily or upon a request from or mandate imposed by the competent Regulatory Authority.

1.138. "**Plan**" means either a Research Plan or the SARS-CoV-2 Development Plan.

1.139. "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.

1.140. "[***] **Option**" has the meaning set forth in Section 5.1.2.

1.141. "**Product Information**" has the meaning set forth in Section 9.1 (Product Information).

1.142. "**Product Labeling**" means, with respect to a Vaccine Product in a country or other jurisdiction in the Territory, (a) the Regulatory Authority-approved full prescribing information for such Vaccine Product for such country or other jurisdiction, including any required patient package insert, instructions for use, or other patient-directed information approved by the competent Regulatory Authority, and (b) all labels and other written, printed, or graphic matter upon a carton, container, or other wrapper utilized with or for such Vaccine Product in such country or other jurisdiction.

1.143. "**Product Specific Foreground IP**" means Foreground IP that specifically relates to a Vaccine Candidate or Vaccine Product (i.e., picture claims), whether patented or patentable (the "**Product Specific Patents**") or not (the "**Product Specific Know-How**").

1.144. "**Product Specific Know-How**" has the meaning set forth in Section 1.140.

1.145. "**Product Specific Patents**" has the meaning set forth in Section 1.140.

1.146. "**Product Trademarks**" means the Trademark(s) to be used by Seqirus or its Affiliates or its or their respective Sublicensees for the Development or Commercialization of Vaccine Candidates or Vaccine Products in the Fields in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates). Product Trademarks do not include the Arcturus Trademarks.

1.147. "**R&D Credit**" shall have the meaning set forth in Section 3.6.3 (R&D Credit).

1.148. "**Regulatory Approval**" means, with respect to a country or other jurisdiction in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize a Vaccine Candidate or Vaccine Product in such country or other jurisdiction, including, where necessary, (a) pricing or reimbursements approval in such country or other jurisdiction, (b) pre-marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) approval of Product Labeling. For the avoidance of any doubt, "**Regulatory Approval**" shall include the receipt of EUA for a Vaccine Candidate or Vaccine Product.

1.149. " **Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (e.g., the FDA, EMA and PMDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Exploitation of the Vaccine Candidates or Vaccine Products in the Territory.

1.150. "**Regulatory Data**" has the meaning set forth in Section 3.7.2 (Regulatory Data).

1.151. "**Regulatory Documentation**" means all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations, and approvals (including Regulatory Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files, but excluding information in the closed section of any DMF submissions with respect to [***] for which [***] will provide to [***] a [***] in such applications or documents, and (c) [***], and [***] in any of the foregoing, in each case ((a), (b), and (c)) relating to a [***].

1.152. " **Research**" means activities up to and including completion of IND-enabling toxicology studies related to the design, discovery, generation, identification, profiling, selection, optimization, characterization, process science, formulation and manufacturing process development cell line development, pre-clinical development or non-clinical or pre-clinical studies of drug candidates, products and components thereof, including Manufacturing in support thereof.

1.153. "**Research Activities**" has the meaning set forth in Section 3.1.1 (Research Plans).

1.154. "**Research Period**" means the period during which either Party is conducting Research Activities.

1.155. "**Research Plan**" means a plan setting forth in reasonable detail specific Research Activities to be performed with respect to the [***], the Party to undertake such Research Activities, the timeline, and the budget for such Research Activities, as well as to the extent applicable Development activities to be conducted with respect to Vaccine Candidates or Vaccine Products in each of the [***] (for clarity, in the case of [***], in addition to [***]) and, with respect to [***] and [***] activities in [***], the [***], the Party to undertake such [***] or [***] activities, and the budget for such [***] or [***] activities.

1.156. "**Research Scale Manufacturing**" means Manufacturing for early-stage Research purposes.

1.157. " [***]" has the meaning set forth in [***].

1.158. "**sa-mRNA**" means [***].

1.159. "[***] **Development Activities**" has the meaning set forth in Section 3.2.1(i) (Development in [***]).

1.160. "[***] **Plan**" means a development plan setting forth [***].

1.161. "**SARS-CoV-2 Field**" means [***].

1.162. "**Selection Term**" means the period beginning on the Effective Date and ending .

1.163. "**Senior Officer**" means, with respect to Arcturus, its Chief Executive Officer or Chief Operating Officer or his/her designee, and with respect to Seqirus, its Chief Operating Officer or his/her designee.

1.164. "**Seqirus**" has the meaning set forth in the preamble hereto.

1.165. "**Seqirus BARDA Agreement**" means the agreement dated as of July 20, 2018 by and between Seqirus and BARDA.

1.166. "**Seqirus Competitor**" means.

1.167. "**Seqirus Foreground IP**" means Foreground IP developed solely by Seqirus or jointly by Arcturus and Seqirus, in either case, that relates specifically to Seqirus' Background IP (except Product Specific Foreground IP). References in this definition to subject matter that is developed by a Party include such subject matter developed by an Affiliate of such Party or a Third Party on behalf of such Party.

1.168. "**Seqirus Improvement Foreground IP**" means Foreground IP developed solely by Seqirus that relates specifically to Arcturus' Background IP (except [***]).

1.169. "**Seqirus Indemnitees**" has the meaning set forth in Section 11.2 (Indemnification of Seqirus).

1.170. "**Seqirus Know-How**" means any and all Know-How under the Seqirus Technology.

1.171. "**Seqirus Patents**" means any and all Patents under the Seqirus Technology.

1.172. "**Seqirus Technology**" means.

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

1.174. "[***]" has the meaning set forth in Section 7.1.2(vi).

1.175. "**Shared COVID Development Costs**" means, [***]:

(a) (i) [***];

(b) [***];

(c) [***]; and

(d) [***].

For clarity, Shared COVID Development Costs shall not include [***] or [***].

1.176. "**Shared FTO Costs**" means the [***] or [***] paid by [***] arising as a result of potential, threatened or actual litigation (whether as plaintiff or defendant) or other proceedings to the extent related to infringement or possible infringement [***] in [***], or the validity or enforceability of any Third Party Patent that [***] in [***] and [***] and [***] paid to [***] in [***], in each case [***]; provided, however, that with respect to [***] in [***], the foregoing shall only be Shared FTO Costs to the [***]. Notwithstanding the foregoing, to the extent any such [***] relate to [***], then [***] shall notify [***] and the portion attributable to Shared FTO Costs shall be reasonably apportioned in good faith by [***].

1.177. "**Shared Net Profits**" means forty percent (40%) of [***] less [***].

1.178. "**Small Lab Scale Manufacturing**" means lab-scale Manufacturing for late-stage Research and early-stage Development purposes.

1.179. "**Sublicensee**" means a Person, other than an Affiliate, a Third Party Provider or a Distributor, that is granted a sublicense by Seqirus under the grants in Section 5.1 (Grants to Seqirus) as provided in Section 5.3 (Sublicenses), except if a court or a governmental agency of competent jurisdiction requires Seqirus to do so (e.g., a compulsory license).

1.180. "**Successful Completion**" means, with respect to a Clinical Study of a Vaccine Candidate or Vaccine Product, the earlier of (a) the last patient last visit for such Clinical Study and[***], and (b) [***].

1.181. "**Supply Agreement**" has the meaning set forth in Section 4.9.1 (Commercial Supply in the [***]).

1.182. "**Technology Transfer Plan**" has the meaning set forth in Section 4.10 (

1.183. "**Term**" has the meaning set forth in Section 12.1.2 (Term).

1.184. "**Terminated Field**" means [***].

1.185. "**Terminated Other Pathogen**" means each [***] with respect to which this Agreement is terminated [***] or otherwise pursuant to Section 12.6 (Termination of [***]), by Seqirus pursuant to Section 12.5 (Additional Termination Rights by Seqirus), or, if this Agreement is terminated in its entirety, all Other Pathogens.

1.186. "**Terminated Product**" means each [***], or, (i) if this Agreement is terminated in its entirety, all [***], (ii) if this Agreement is terminated with respect to [***], all [***], or (iii) if this Agreement is terminated with respect to [***], all [***] with respect to such [***]; provided, however, that any [***] with respect to which the Payment Term has expired shall not be a Terminated Product.

1.187. "**Territory**" means the entire world.

1.188. "**Third Party**" means any Person other than Arcturus, Seqirus and their respective Affiliates.

1.189. "**Third Party Claims**" has the meaning set forth in Section 11.1 (Indemnification of Arcturus).

1.190. "**Third Party Patent**" means a Patent issued to any Third Party.

1.191. "**Third Party Provider**" has the meaning set forth in Section 3.5 (Subcontracting).

1.192. "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.193. "**United States**" or "**US**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.194. "**Vaccine Candidate**" [***].

1.195. "**Vaccine Product**" means any Vaccine Candidate selected by Seqirus for Commercialization within the Territory for the prevention or prophylaxis of a disease caused by a particular pathogen in the Fields. [***]

1.196. "**Valid Claim**" means (i) a claim of a granted or issued Patent in the Arcturus Licensed IP (including any extension or supplementary protection certificate) in the relevant country which is in force and which has not been declared invalid or held invalid or unenforceable by a patent office or other government authority of competent jurisdiction, or (ii) a pending claim of an unissued pending patent application within the Arcturus Licensed IP, provided that in each case such pending claim shall cease to be a Valid Claim after the date that is [***] . A claim of a granted or issued Patent that is declared or found invalid by a patent office, court or other tribunal shall not be considered a Valid Claim unless it is subsequently reinstated at which point [***] will calculate and [***] (if [***]) as if [***] had been [***]. Notwithstanding the foregoing, Valid Claim does not include any claim that is [***] solely developed by Seqirus, Product Specific Foreground IP or Seqirus Improvement Foreground IP.

1.197. "**Working Group**" has the meaning set forth in Section 2.5 (Working Groups).

ARTICLE 2
COLLABORATION MANAGEMENT

2.1 **Joint Development Committee**.

2.1.1 **Formation**. As soon as practicable after the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**"). The JDC shall consist of [***]representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC. From time to time, each Party may substitute one (1) or more of its representatives to the JDC on written notice to the other Party. [***].

2.1.2 **Specific Responsibilities**. The JDC shall [***] of Vaccine Candidates and Vaccine Products. In particular, the JDC shall:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***];

(h) [***];

(i) [***]; and

(j) [***].

2.2 **General Provisions Applicable to the JDC**.

2.2.1 **Meetings and Minutes**. The JDC shall meet [***], or as otherwise agreed to by the Parties, the meeting may be virtual with a least [***] meeting [***] at a physical location with the location of such meetings alternating between locations designated [***]. The co-chairpersons, or chairperson, as applicable, of the JDC shall be responsible for calling meetings on no less than [***] notice or such shorter notice period as agreed upon by the Parties. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least [***] in advance of the applicable meeting; provided, that under exigent circumstances requiring input by the JDC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld or delayed. The co-chairpersons, or chairperson, as applicable, of the JDC shall prepare and circulate for review and approval of the Parties minutes of each meeting within [***] after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JDC.

2.2.2 **Procedural Rules**. The JDC shall have the right to adopt such standing rules as necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JDC shall exist whenever there are present at a meeting at least [***]. Representatives of the Parties on the JDC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed with [***] notice. The JDC shall take action by [***]. Employees or consultants of either Party that are not representatives of the Parties on the JDC may attend meetings of the JDC, with [***] notice; provided, that such attendees (i) shall not [***].

2.2.3 **Dispute Resolution**. If the JDC cannot, or do not, reach consensus on an issue at a meeting, then a Party may refer such matter to the Parties' respective Senior Officers for resolution, in which case the Senior Officers will use good faith efforts to resolve any such matter so escalated to them as soon as practicable but in any event within [***] after such matter is escalated to them, and any final decision that the Senior Officers agree to in writing will be conclusive and binding on the Parties. If the Senior Officers are unable to reach agreement on any such matter so referred within [***] after such matter is referred to them (or such longer period as the Senior Officers may agree upon), [***]. Disputes arising between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, and that are outside of the jurisdiction of the JDC, shall be resolved pursuant to Section 13.6 (Dispute Resolution).

2.2.4 **Limitations on Authority**. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JDC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JDC shall not have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 13.8 (Entire Agreement; Amendments) or compliance with which may only be waived as provided in Section 13.11 (Waiver and Non-Exclusion of Remedies).

2.2.5 **Alliance Manager**. Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the JDC and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. [***].

2.3 **Discontinuation of Participation on the JDC**. The JDC shall continue to exist until [***] .

2.4 **Interactions Between the JDC and Internal Teams**. The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Nothing contained in this Article shall (i) prevent a [***] or (ii) require

2.5 **Working Groups**. From time to time, the JDC may establish and delegate duties to sub-committees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities (for example, joint project team, and/or [***]). Each such Working Group shall be constituted and shall operate as the JDC determines; provided that each Working Group shall have equal representation from each Party, unless otherwise mutually agreed. Working Groups may be established on an ad hoc basis for purposes of a specific project or on such other basis as the JDC may determine. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the JDC. In no event shall the authority of the Working Group exceed that specified for the JDC pursuant to this Article. [***] .

2.6 **Expenses**. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise prepare for, and participate on, the JDC or other Working Group.

ARTICLE 3
RESEARCH AND DEVELOPMENT

3.1 **Research Activities**.

3.1.1 **Research Plans**. Attached hereto as Schedule 3.1.1 is the Research Plan for the program of Research with respect to [***] in the [***]. The Research Plans will allocate responsibility between [***] for the conduct of activities thereunder (such activities,

"**Research Activities**"). Unless [***] otherwise agrees in writing, all Research Activities shall be designed and implemented so as to [***], [***], the [***], and [***].

3.1.2 **Updates; Amendments**. The Parties acknowledge that the Research Plans attached as of the Effective Date may be [***]. Promptly following the Effective Date, the Parties shall [***]. The JDC shall review each Research Plan covering all Research Activities at [***] for the purpose of considering appropriate amendments thereto. In addition, [***] , through its representatives on the JDC, may [***] at any time.

3.1.3 **Diligence Obligations**. Subject to the limitations in Section 4.3 (Diligence), each of [***] shall perform the Research Activities allocated to it under a Research Plan. For avoidance of doubt, [***] warrants that any particular result will be achieved. In furtherance of [***] Research Activities in the [***], [***] shall use [***] to meet the [***] for [***] set forth in [***]; provided, that, the [***] of [***] in the event that [***] does not [***] is that [***] will have the right, by written notice within [***] after such non-achievement, to terminate this Agreement solely with respect to [***] that is [***] that [***]did not meet; provided, however, that [***] shall have the right with respect to each [***] to extend the time period for the applicable [***] set forth in [***] by [***] upon (i) the payment of [***] ([***]) and (ii) delivery of notice to [***] certifying that [***] is not developing, and will not during such [***] period develop, a [***].

3.1.4 **Compliance**. All Research Activities shall be performed, or caused to be performed, in good scientific manner and in compliance with all Applicable Laws. In furtherance of the prior sentence, each Party will employ or engage Persons with appropriate education, knowledge and experience to conduct and oversee its Research Activities.

3.1.5 **Records, Reports and Information**.

(i) During the Research Period, each Party shall provide to the JDC: (i) on a [***], a written summary presentation regarding the activities performed by it under a Research Plan for [***] in the prior [***] and activities being planned for the [***] under a Research Plan and (ii) on, a written report regarding the activities performed by it under a Research Plan in the prior [***] and activities being planned for the forthcoming [***]. Each presentation or report shall summarize in reasonable detail [***]. Each report shall be structured as follows: [***]. Such presentations and reports will be accurate and will contain raw data from studies carried out by or on behalf of such Party. Each Party will provide the members of the JDC with copies of all slide decks and reports they intend to present at a JDC meeting. [***].

(ii) During the Research Period, each Party shall, and shall ensure that its Third Party Providers, maintain scientific records, accounts, notes, reports and data with respect to its Research activities, in accordance with Applicable Law, standard pharmaceutical industry practices (including as appropriate to the stage of Development, GCP and GMP) and standard practices applied by such Party in similar circumstances (which practices [***]), and in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of the Research Activities under each Research Plan; provided such records shall be maintained for [***] after the termination of this Agreement, or for such longer period as may be required by

Applicable Law. Upon request by a Party, the other Party shall provide copies of the records it has maintained pursuant to this Section 3.1.5(ii) to the requesting Party, including primary data and notebooks. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all records of the other Party maintained pursuant to this Section 3.1.5(ii). The requesting Party shall maintain such records and the information disclosed therein in confidence in accordance with ARTICLE 9 (Confidentiality And Non-Disclosure). [***].

3.1.6 **Materials Transfer**. In order to facilitate the activities contemplated under a Research Plan, either Party may provide to the other Party certain biological materials, chemical compounds or any other materials (collectively, "**Materials**") for use by the other Party in furtherance of the Research Plans. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the activities conducted in accordance with the Research Plans, will not be used or delivered to or for the benefit of any Third Party (except for Third Party Providers as permitted under this Agreement in furtherance of the Research Plans or as provided in Section 3.5 (Subcontracting)), without the prior written consent of the supplying Party, and will be used in compliance with Applicable Law. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. The supplying Party will provide the other Party the most current material safety data sheet for the Materials upon transfer of any Materials. The supplying Party will be responsible for complying with all export laws and regulations applicable to the transfer of such Materials. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR, EXCEPT AS SET FORTH IN ARTICLE 10 (REPRESENTATIONS, WARRANTIES AND COVENANTS), ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

3.1.7 **Adverse Event Reporting**. Each Party shall be responsible for the monitoring and reporting of safety information, if any, generated in the conduct of its Research activities and will promptly report such information to the other Party.

3.2 **Development Activities**.

3.2.1 **Responsibility for Development;** [***] .

(i) **Development in the** [***]. Attached hereto as Schedule **3.2.1** is the **[***]** for the **[***]** with respect to **[***]** in the **[***]**, which Plan allocates responsibility between **[***]**. The Parties shall use **[***]** to conduct the **[***]** in accordance with the terms and conditions of this Agreement and the **[***]**. For avoidance of doubt, the **[***]** Activities may include activities such as **[***]** (such as [***]).

(ii) **Development in** [***] **(other than** [***]**)**. As of the Effective Date, each of the Parties shall be responsible, at Seqirus' sole cost and expense, for all

Development activities allocated to it to be conducted under this Agreement with respect to the **[***]**.

3.2.3 **Updates; Amendments**. Promptly following the Effective Date, the Parties shall review and mutually agree on any additional details and updates to the activities under the [***]. The JDC shall review the [***] as set forth in Section 2.1.2 (Specific Responsibilities) at [***] for the purpose of considering appropriate amendments thereto. In addition, either Party, through its representatives on the JDC, may propose amendments to the [***] at any time. In the event of [***].

3.2.4 [***] **Development Obligations of Arcturus**. Arcturus shall, in consideration of the payment commitments given under this Agreement and on the terms and conditions of this Agreement, and as provided in the [***], undertake the [***] work that may be deemed necessary to support the [***] in the [***] in [***] as [***] and [***] to support the filing of Drug Approval Applications in order to obtain Regulatory Approvals for the [***] in [***] as [***]. Such activities include undertaking [***]. [***] will support [***] on filings in other countries as agreed in good faith by and between [***]. In the event that [***] determine to have [***] undertake a [***] y, or any other activities not reflected in the [***] , then the Parties will amend the [***] in accordance with Section 3.2.2 (Updates; Amendments). For avoidance of doubt, (i) if the Parties determine to have Arcturus undertake a [***] Study, then the costs thereof shall be treated in a manner similar to that of the [***] in accordance with Section 3.6.2(i), and (ii) except to the extent otherwise expressly agreed in writing by the Parties, [***].

3.2.5 **Diligence Obligations.** Subject to the limitations in Section 4.3 (Diligence), each of [***] and [***] shall use [***] to perform the [***] conducted by it under the [***] or otherwise in accordance with this Agreement in the [***] in the Territory.

3.2.6 **Compliance**. Each Party shall perform, or cause to be performed, any and all of its Development activities under this Agreement, in good scientific manner and in compliance with all Applicable Laws.

3.2.7 **Reports**.

(i) Each Party shall provide to the JDC [***] and (ii) [***]. In addition, the Parties will promptly notify each other of any material developments during the performance of their activities under the [***]. Each Party will provide the members of the JDC with copies of all slide decks and reports they intend to present at a JDC meeting.

(ii) Notwithstanding this Section 3.2.6, neither Party shall be required to undertake activities, or generate or produce data or information, that are not specified in the or otherwise agreed in writing by the Parties.

(iii) Except with respect to Development activities related to [***] under the [***] , each Party shall provide to the JDC (i) [***], and (ii) [***]. Each Party will provide the members of the JDC with copies of all slide decks and reports they intend to present at a JDC meeting.

(iv) Arcturus shall provide Seqirus with any results (including the data) arising from any Research or Development of Vaccine Candidates or Vaccine Products, including the rationale for the selected constructs, lipid components and the Manufacturing Process selection that may be necessary or useful in connection with (a) Seqirus being able to make rational decisions throughout the process of Vaccine Candidate or Vaccine Product Research and Development, (b) Manufacturing Technology Transfer and Manufacturing Process scale-up, process modifications and improvements, or (c) justifying to any Regulatory Authority the rationale for Vaccine Candidate or Vaccine Product formulation, Manufacturing Process or Research and Development process.

3.3 **Arcturus R&D Support Period**. During the first [***] following the Effective Date (the "**Arcturus R&D Support Period**") and to the t, Seqirus shall utilize,[***]

3.4 **Pre-Clinical and Clinical Supply of Vaccine Candidates or Vaccine Products**.

3.4.1 [***] **Field**. [***] shall, as and to the extent reasonably requested by [***] or as set forth in a Plan, supply [***] of [***] for use by [***] in the Research and Development activities in the [***] Field in accordance with the applicable Plan and in compliance with [***] specifications (determined reasonably by [***]) and GMP. [***]). Unless otherwise set forth in a Plan, [***] shall Manufacture all [***] and [***] delivered by it pursuant to this Section 3.4.1 pursuant to GMP.

3.4.2 [***] **Field,** [***] **Field and** [***] **Field.** Except as otherwise agreed or set forth in the applicable Research Plan, [***] shall be responsible for the pre-clinical and clinical supply requirements of the Vaccine Candidates or Vaccine Products and placebo for use by, and by [***] and [***] in the Research Activities, in [***], in accordance with the applicable Plan in compliance with [***] and GMP. [***]).

3.5 **Subcontracting**. Each Party shall have the right to subcontract any of its Research or Development activities to a Third Party (a "**Third Party Provider**"); provided, that, with respect to Arcturus, it will not subcontract any of its obligations hereunder unless it furnishes with advanced written notice thereof and an opportunity to consult regarding such subcontractor and the terms of such subcontract, which notice shall specify the work to be subcontracted and the reason for subcontracting, and (c) it obtains a written undertaking from the Third Party Provider that is consistent with the applicable terms and conditions of this Agreement, including the confidentiality provisions of ARTICLE 9 (Confidentiality And Non-Disclosure). With respect to [***] Field, subcontracting shall be included in [***].

3.6 **Research and Development Costs**.

3.6.1 **Responsibility for Costs Relating to Research and Development Activities in** [***]**,** [***] **Field and** [***] **Field**. This Section 3.6.1 only applies to [***].

(i) Unless otherwise agreed by [***] and set forth in the applicable Research Plan, and subject to Section 3.6.3 (R&D Credit) and Section 5.6.2 (BARDA). [***] shall be responsible for and shall bear all costs incurred in connection with the

performance of any Research or Development activities in the [***], which shall be conducted in accordance with each applicable Plan.

(ii) [***] shall report to [***], within [***] after the end of each [***], incurred by it during such [***]. Such report shall specify in reasonable detail all amounts included in such [***] during such [***] ([***]) and shall be accompanied by [***]. Each such report shall enable [***] to compare the reported costs against the budgets in the applicable Plan, on [***] for [***]. With respect to each report, [***] shall seek to resolve any questions related to such accounting statements within [***] ([***]) [***] following receipt by [***] of [***] report hereunder.

(iii) following or concurrent with the delivery of each report under clause (ii) of this Section 3.6.1. pay the undisputed invoice amounts within [***] of receipt of invoice thereof. only dispute invoice amounts in good faith and by providing written notice.

3.6.2 **Responsibility for Funding Costs Relating to Research and Development Activities in** [***] **Field**. This Section 3.6.2 only applies to the [***] Field.

(i) [***] **Development**. Subject to the terms of this Agreement (including payment of milestone payments under Section 6.3 (Development Milestones)), [***] shall be responsible for funding [***] ([***]) of the [***] Research and Development in the [***] Field as set forth in the [***] and Section 3.2.3 ([***] Field Development Obligations of [***]).

(ii) [***] **Development**.

a) Subject to the terms of this Agreement (including payment of milestone payments under Section 6.3.1(ii) through 6.3.1(viii) and the determination of [***] in accordance with Section 6.5), be responsible for funding one hundred percent (100%) of the Research and Development of the [***] Product in the [***] Field allocated to be conducted by Arcturus in the [***] as of the Effective Date (along with any additional activities related to the for which the Parties agree in an amended [***] shall be funded by).

b) For avoidance of doubt, shall be responsible for funding one hundred percent (100%) of the [***] in the [***] Field as set forth in the [***] .

c) [***] of such [***] described in clauses (a) and (b) of this Section 3.6.2(ii) shall be applied by [***] to [***].

(iii) **Additional Development**. Except as set forth in clauses (i) and (ii)) above, [***] shall be responsible for funding [***]of any additional Research and Development in the [***] Field. [***]. Any such additional Research and Development conducted by in the manner set forth in Section 3.6.1(ii) and 3.6.1(iii).

3.6.3 **R&D Credit**. with [***] in credit (“**R&D Credit**”) toward Research and Development Expenses conducted during the . will allocate the R&D Credit as it deems necessary to fulfill the activities set forth in the Research Plans (but, for the avoidance

of doubt, not as a credit against any milestone payments). If any R&D Credit is unused as of the end of the.

3.6.4 **FTE Costs**. Each Party shall record and account for its FTE Costs and [***] for the [***] or [***], as applicable, in each case, using [***]. Out-of-pocket costs allocable to [***] that are [***] or [***], respectively.

3.6.5 **Cost Overruns**.

(a) Each Party shall promptly inform the other Party upon its determining that it is likely to overspend or underspend by [***].

(b) The portion of any overspend that is less than or equal to [***] of such Party's respective aggregate budgeted costs and expenses for Research activities or Development activities set forth in the applicable Plan shall be handled pursuant to Section 3.6.1 ([***]) or Section 3.6.2 ([***]), as the case may be (as if such overspend had been included in amounts contained in such Plan), and, if related to the [***] Field, included in.

(c) If either Party exceeds its aggregate budgeted costs and expenses by [***], such Party [***]. If and to the extent that any such overspend in excess of [***] was outside the reasonable control of such Party and not caused by its negligence or willful misconduct, then provided that such Party has promptly notified the other Party of such overspend (the "**Permitted Additional Overspend**") and used reasonable efforts to mitigate the size of such overspend shall be handled pursuant to Section 3.6.1 or Section 3.6.2, as the case may be (as if such overspend had been included in the amounts contained in such Plan), and if related to the [***] Field, included in the.

(d) To the extent that any overspend is not a Permitted Additional Overspend, the Party performing the activities that resulted in the overspend shall be solely responsible for the overspend.

3.7 **Regulatory Matters**.

3.7.1 **Regulatory Activities**.

(i) [***] **Field,** [***] **Field and** [***] **Field**.

a) As between the Parties, shall have the sole right to prepare, obtain, and maintain the Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions, and to conduct communications with the Regulatory Authorities, for [***] in [***], in [***] (which shall include [***]), except that, prior to with respect to the [***], any [***] production methods may be submitted to Regulatory Authorities by or its agent through a drug master file (DMF) which shall be authorized to reference in its Drug Approval Applications, as may be appropriate., as may be reasonably necessary, in obtaining and maintaining Regulatory Approvals for the [***] in the [***] Field, [***] and [***] Field, and in the activities in support thereof, including providing necessary documents or other materials required by Applicable Law to obtain Regulatory Approvals, and providing responses to regulatory questions, in each case in accordance with the

terms and conditions of this Agreement. Arcturus shall respond to such requests from Seqirus as soon as possible and no later than [***] before the time limit (provided that), if any, set forth by Regulatory Authorities for providing such materials or information, or such other date as agreed in writing by the Parties. The Parties shall keep each other reasonably informed with respect to manufacturing or quality changes as long as the the DMF or any other part of a Vaccine Product or Vaccine Candidate manufacture process is conducted by is included in the JDC's annual review of the applicable Plan covering such filing, or if it is subject to the Supply Agreement and Quality Agreement. shall have the right to review and provide feedback on regulatory filings that will be submitted to Regulatory Authorities by.

.

b) All Regulatory Documentation (including all Regulatory Approvals and Product Labelling) relating to the [***] in the [***] Field, [***] Field and [***] Field in [***] shall be owned by, and shall be the sole property and held in the name of, or its designated Affiliate, Sublicensee or designee. all of its right, title, and interest in and to all Existing Regulatory Documentation relating to the [***] in the [***] Field, [***] Field and [***] Field in [***], to the extent applicable, and all other Regulatory Documentation relating to such subject matter as may be Controlled by Arcturus from time to time during the Term. Arcturus shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as Seqirus may reasonably request in connection with, or to carry out more effectively the purpose of, or to better assure and confirm unto Seqirus its rights under, this Section 3.7.1(i)b)..

(ii) [***] **Field**.

a) Arcturus shall undertake to prepare, obtain, and maintain the Drug Approval Applications, other Regulatory Approvals and other submissions, and conduct communications with the Regulatory Authorities, for [***] and [***] in the [***] Field, in [***], in accordance with the [***] and the Development and Commercialization strategy determined by. Arcturus shall undertake to prepare, obtain, and maintain the Drug Approval Applications, other Regulatory Approvals and other submissions, and conduct communications with the Regulatory Authorities, for [***] Field, in the [***], in accordance with the [***] and the Development and Commercialization strategy determined by. shall have the right to prospectively review and provide feedback on decisions, strategies, regulatory filings or other information that will be shared with or submitted to Regulatory Authorities by shall incorporate all such feedback in such filings or other information; provided, that, with respect to any such feedback with which. [***]

b) Except as set forth in the shall have the sole right to prepare, obtain, and maintain the Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions, and to conduct communications with the Regulatory Authorities, for [***] in the [***] Field, in other countries or other jurisdictions in the Territory (which shall include filings of or with respect to INDs and other filings or communications with the Regulatory Authorities with respect to the Research and Development activities). Arcturus shall support Seqirus, as may be reasonably necessary, in obtaining Regulatory Approvals for the Vaccine Candidates or Vaccine Products in the [***]

Field, and in the activities in support thereof, including providing necessary documents or other materials required by Applicable Law to obtain Regulatory Approvals (which shall include authorizations to reference any Regulatory Documentation held by Arcturus or its manufacturing partners necessary or useful for the Manufacture of Vaccine Candidates or Vaccine Products), in each case in accordance with the terms and conditions of this Agreement..

c) All Regulatory Documentation (including all Regulatory Approvals and Product Labelling) relating to the [***] in the [***] Field in [***] shall be owned by, and shall be the sole property and held in the name of, or its designated Affiliate, Sublicensee or designee. all of its right, title, and interest in and to all Existing Regulatory Documentation (including any existing Regulatory Approvals) and all other Regulatory Documentation Controlled by Arcturus from time to time during the Term. Arcturus shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as Seqirus may reasonably request in connection with, or to carry out more effectively the purpose of, or to better assure and confirm unto Seqirus its rights under, this Section 3.7.1(ii)c)..

3.7.2 **Regulatory Data**. shall promptly provide to copies of or access to all non-clinical data and Clinical Data, CMC Data (except as otherwise expressly set forth in this Agreement with respect to a other Information, results, Regulatory Documentation and analyses that are Controlled by Arcturus or any of its Affiliates, that pertain to any Vaccine Candidate or Vaccine Product (collectively, "**Regulatory Data**"), when and as such Regulatory Data becomes available. Without limiting the foregoing, shall, within [***] of the Effective Date, provide to Seqirus, in such form and format as Seqirus may reasonably request, (i) copies of all correspondence, as of the Effective Date, to and from any Regulatory Authority that relates to the [***] in the Fields, and (ii) all Regulatory Documentation assigned to Seqirus pursuant to Section 3.7.1(i)b) and Section 3.7.1(ii)c)..

3.7.3 **Regulatory Approval Transition Process for** [***] **in the** [***] **Field**. Following the successful submission of Drug Approval Applications by under Section 3.7.1(ii) and receipt of initial Regulatory Approvals in [***] for [***] and any in the [***] Field in the [***], the Parties shall in good faith coordinate the transition of ownership of [***] from (which may include the transition of post-marketing clinical trials and third-party manufacturing agreements and the wind down the submission of certain regulatory filings). Each Party shall be responsible for its own costs of such transitional activities.

ARTICLE 4
COMMERCIALIZATION

4.1 **General**. Seqirus (itself or through its Affiliates or Sublicensees) shall have the sole right to Commercialize Vaccine Products in the Territory at its own cost and expense (except as otherwise expressly set forth herein).

4.2 **Commercialization**. During the Term, [***]. Arcturus shall not make any public statement with respect to Commercialization of Vaccine Products in the Territory without prior written consultation with Seqirus, allowing Seqirus reasonable time to comment on such

proposed public statement, and Arcturus shall reflect such comments as may be provided by Seqirus in such public statement prior to its release.

4.3 **Diligence**. Seqirus shall use [***] to [***] in the Fields within the Territory. Arcturus acknowledges and agrees that (A) the Commercialization of a Vaccine Product may be delayed, suspended or otherwise modified by Seqirus in response to circumstances outside the reasonable control of Seqirus, including force majeure events described in Section 13.1 (Force Majeure), (B) Seqirus shall have the right to satisfy its diligence obligations under this Section 4.3 (Diligence) through its Affiliates or Sublicensees (provided for clarity, that the engagement of an Affiliate or Sublicensee shall not diminish the level of), and (C) nothing in this Section 4.3 (Diligence) is intended, or shall be construed, to require.

4.4 **Booking of Sales; Distribution**. Seqirus shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute [***] in the Fields in the Territory and to perform or cause to be performed all related services. Seqirus shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to [***] in the Fields in the Territory. Seqirus and Arcturus shall promptly notify each other of any returns, recalls or withdrawals, or other events or activities of which it becomes aware that would be reasonably likely to materially adversely affect the sales of [***] in the Fields in the Territory.

4.5 **Product Trademarks**. Subject to Section 4.6 (Markings), Seqirus shall have the sole right to determine and own the Product Trademarks to be used with respect to the Commercialization of the Vaccine Products in the Territory. Subject to the terms and conditions of this Agreement,") solely in connection with the Exploitation of the Vaccine Candidates and Vaccine Products in the Territory in accordance with this Agreement. Arcturus retains the right to use by itself or license to Third Parties the right to use the Arcturus Trademark in relation to pharmaceutical products other than the Vaccine Products. Seqirus agrees that the nature and quality of the Vaccine Products Exploited by it under the Arcturus Trademarks, together with all related advertising, promotional and other related uses of the Arcturus Trademarks by Seqirus, shall conform in all respects with the trademark guidelines Seqirus follows in respect of its own proprietary trademarks (and consistent with trademark guidelines of Arcturus). Seqirus shall follow Arcturus's brand guidance (which Arcturus may provide Seqirus from time to time) in using Arcturus Trademarks. Arcturus will have the right to monitor Seqirus' use of the Arcturus Trademarks and to request that Seqirus correct any failure to comply with this Section 4.5 which Arcturus reasonably determines is likely to adversely affect the strength or value of such trademark, such request not to be unreasonably refused. All goodwill in the use of the Arcturus Trademarks shall inure to the benefit of Arcturus.

4.6 **Markings**. To the extent allowed by Applicable Law in a country or other jurisdiction in the Territory, the Product Labelling for [***] in the [***] Field used by Seqirus and its Affiliates in connection with the Commercialization thereof in such country or other jurisdiction shall.

4.7 **Distributorships**. Seqirus shall have the right, in its sole discretion, to appoint its Affiliates, and Seqirus and its Affiliates shall have the right, in their sole discretion, to appoint any other Persons, in the Territory or in any specific country or other jurisdiction of the Territory,

to distribute, market, and sell the Vaccine Products in the Fields (with or without packaging rights), in circumstances where the Person purchases its requirements of Vaccine Products from Seqirus or its Affiliates but does not otherwise make any royalty or other payment to Seqirus or any Affiliate of Seqirus with respect to its Intellectual Property or other proprietary rights. Where Seqirus or its Affiliates appoints such a Person and such Person is not an Affiliate of Seqirus,. The term "packaging rights" in this Section 4.7 (Distributorships) means the right for the Distributor to package Vaccine Products supplied in unpackaged bulk form into individual ready-for-sale packs.

4.8 **Commercial Supply in the** [***]. Subject to Section 4.10 (Manufacturing Technology Transfer Upon Seqirus' Request), shall be solely responsible for the Manufacturing and supply of the Vaccine Candidates and Vaccine Products in [***] for commercial purposes.

4.9 **Commercial Supply in the** [***] **Field**.

4.9.1 Not later than [***] after the Effective Date (to be effective not earlier than the Effective Date), Seqirus and Arcturus shall enter into a supply agreement pursuant to which, subject to Section 4.10 (t), Arcturus shall supply to Seqirus the Vaccine Candidates and Vaccine Products in the [***] Field (the "**Supply Agreement**") in such quantities as Seqirus may order in accordance with the terms and conditions of such agreement. The Supply Agreement shall contain the terms set forth in Schedule 4.9
(Commercial Supply in the [***] Field) and such additional terms as are reasonable and customary for similar supply agreements that shall be negotiated and agreed by the Parties in good faith. In the event that the Parties are not able to agree on such additional terms to be included in the Supply Agreement by the date that is [***] after the Effective Date, such additional terms shall be determined in accordance with Section 13.6 (Dispute Resolution)., discussions with its for the provision of manufacturing and supply services to necessary for the manufacture of Vaccine Candidates and Products and, to the extent practicable, the assignment or novation of any such contracts to Seqirus.

4.10 **Manufacturing Technology Transfer** . shall have the right, at any time and from time to time after the Effective Date, to) of (i) the then-current process for the Manufacture of the [***] in the [***] Field, including Research Scale Manufacturing, Small Lab Scale Manufacturing and Large Scale Manufacturing of [***] and any [***] in the [***] Field, and (ii) no earlier than [***] (with respect to each such Field, the "**Manufacturing Process**") and to implement the Manufacturing Process at facilities designated by (such transfer and implementation, as more fully described in this Section), with respect to each such Field, the "**Manufacturing Technology Transfer**"), in accordance with a technology transfer plan to be agreed upon by the Parties and incorporated herein as Schedule 4.10 (the "**Technology Transfer Plan**"); provided that Arcturus shall not be required to conduct more than [***] Manufacturing Technology Transfers . Arcturus shall provide, and shall use Commercially Reasonable Efforts to cause its Third Party manufacturers to provide (including by negotiating contractual obligations for such Third Party manufacturers to do so under agreements entered into following the Effective Date), all reasonable assistance requested by Seqirus to enable Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) to implement the Manufacturing Process at the facilities designated by Seqirus. If requested by Seqirus, such assistance shall include facilitating the entering into agreements with applicable Third Party suppliers relating to the

Vaccine Candidates and Vaccine Products in the applicable Field. Without limitation to the foregoing, in connection with each Manufacturing Technology Transfer:

4.10.1 Except for [***], of such Manufacturing Technology Transfers, including [***] .

4.10.2 Seqirus acknowledges the sensitive proprietary nature of Manufacturing information relating to the [***]. Arcturus acknowledges the interest that Seqirus has in ensuring control of its supply chain for the Manufacture of Vaccine Candidates and Vaccine Products. Therefore, the Parties will, at the request of Seqirus, discuss in good faith through the JDC approaches to address the interests of both Parties, and the JDC shall have the right to determine whether and how a Manufacturing Technology Transfer with respect to the [***] would occur.

4.10.3 As part of each Manufacturing Technology Transfer, Arcturus shall make available, and shall use Commercially Reasonable Efforts to cause its Third Party manufacturers and suppliers to make available (including by negotiating contractual obligations for such Third Party manufacturers to do so under agreements entered into following the Effective Date), to Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable), all Manufacturing-related Arcturus Know-How, Information and materials relating to the Manufacturing Process, and all documentation constituting material support (provided that such documentation does not contain restricted Third Party confidential information), standard operating procedures, specifications as to materials to be used and control methods, that are reasonably necessary or useful to enable Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process at the applicable facility;

4.10.4 Arcturus shall cause all appropriate employees and representatives of Arcturus and its Affiliates to meet with, and shall use Commercially Reasonable Efforts to cause all appropriate employees and representatives of its Third Party manufacturers to meet with (including by negotiating contractual obligations for such Third Party manufacturers to do so under agreements entered into following the Effective Date), employees or representatives of Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) at the applicable manufacturing facility at mutually convenient times to assist with the working up and use of the Manufacturing Process and trouble-shooting during and after completion of the transfer, and with the training of the personnel of Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) to the extent reasonably necessary or useful to enable Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process;

4.10.5 Without limiting the generality of Section 4.10.4 above, Arcturus shall cause all appropriate analytical and quality control laboratory employees and representatives of Arcturus and its Affiliates to meet with, and shall use to cause all appropriate analytical and quality control employees and representatives of its Third Party manufacturers to meet with (including by negotiating contractual obligations for such Third Party manufacturers to do so under agreements entered into following the Effective Date), employees or representatives of Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable)

at the applicable manufacturing facility and make available all necessary equipment, at mutually convenient times, to support and execute the transfer of all applicable analytical methods and the validation thereof (including, all applicable Arcturus Know-How, methods, validation documents and other documentation, materials and sufficient supplies of all primary and other reference standards);

4.10.6 to cause its Third Party manufacturers and suppliers to take such steps (including by negotiating contractual obligations for such Third Party manufacturers to do so under agreements entered into following the Effective Date), as are reasonably necessary or useful to assist in reasonable respects Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) in obtaining any necessary licenses, permits or approvals from Regulatory Authorities with respect to the Manufacture of the Vaccine Candidates and Vaccine Products in the applicable Field at the applicable facilities;

4.10.7 Arcturus shall provide, and shall [***] Third Party manufacturers to enable Arcturus to provide (including by negotiating contractual obligations for such Third Party manufacturers and suppliers to do so under agreements entered into following the Effective Date), such other assistance as Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) may reasonably request to enable Seqirus (or its Affiliate or designated Third Party manufacturer, as applicable) to implement and maintain the Manufacturing Process at the receiving facility to Manufacture Vaccine Candidates and Vaccine Products in the applicable Field;

4.10.8 [***]

4.10.9 [***]

4.10.10 **Subsequent Manufacturing Process Improvements**. [***].

ARTICLE 5
GRANT OF RIGHTS

5.1 **Grants to Seqirus**. Subject to Section 5.6 (Exceptions to Seqirus Rights) and the rights (including any sublicensed rights) granted by Arcturus under [***], and the licenses granted by Seqirus to Arcturus under Section 5.2, Arcturus (on behalf of itself and its Affiliates) hereby grants to Seqirus:

5.1.1 an exclusive (including with regard to Arcturus and its Affiliates) license (or sublicense), with the right to grant sublicenses in accordance with Section 5.3 (Sublicenses) under the Arcturus Licensed IP, to (i) Research, Develop, have Developed, Manufacture, and have Manufactured, Vaccine Candidates and Vaccine Products worldwide for Commercialization in the Territory, and (ii) Commercialize and have Commercialized Vaccine Products in the Territory; in each case, in the [***], and in the event an exclusive license is granted for a specific pathogen under Section 5.1.2, on a, the [***] Field. For clarity, this license and the foregoing exclusivity shall extend to Vaccine Candidates and Vaccine Products as part of Combination Vaccines, but nothing in this Section 5.1 shall be interpreted as granting Seqirus a license to use Arcturus Licensed IP outside of the Fields or as prohibiting Arcturus from

developing vaccines (other than Vaccine Candidates and Vaccine Products) outside of the Fields using the Arcturus Licensed IP;

5.1.2 a non-exclusive license (or sublicense) (except that, with respect to Product Specific Patents and Arcturus Patents invented solely by Seqirus, such license or sublicense shall be exclusive), with the right to grant sublicenses in accordance with Section 5.3 (Sublicenses), under the Arcturus Licensed IP, to (i) [***], have [***] [***] for [***] in the Territory and (ii) Commercialize and have [***] in the [***] Field in the Territory. Seqirus will have an option to convert any [***] Field, ("[***] **Option**"). In such circumstances, Arcturus agrees to grant no further licenses, or no other licenses (where no licenses have been granted to any Third Party as of the election date) following Seqirus exercising its [***] Option in respect of the applicable pathogen. Arcturus agrees that it will not, after the Execution Date, grant to a Third Party an exclusive license to any pathogen in the [***] Field; provided that the foregoing shall not apply to any exclusive license to a pathogen granted before such pathogen has become part of the [***] Field; and

5.1.3 subject to Section 7.1.3 (Ownership of Corporate Names), a non-exclusive license, with the right to grant sublicenses in accordance with Section 5.3 (Sublicenses), to use Arcturus' Corporate Names solely as required to comply with Section 4.6 (Markings) and for no other purpose.

5.2 **Grants to Arcturus**. Subject to Section 5.3 (Sublicenses), , in each case solely for the purpose of performing its obligations under this Agreement or the Supply Agreement. Such license shall be if needed in order to perform their obligations under this Agreement or the Supply Agreement. Arcturus shall be entitled to use Third Party Providers as provided in this Agreement.

5.3 **Sublicenses**. Seqirus shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the licenses and rights of reference granted in Section 5.1 (Grants to Seqirus), to its Affiliates and other Persons; provided that any such sublicenses shall be consistent with the terms and conditions of this Agreement. No sublicense shall relieve or waive any obligations of Seqirus hereunder. Seqirus shall remain responsible for the performance by such Sublicensee of the rights and obligations hereunder. In respect of such sublicenses (or sub-sublicenses) and without limiting the foregoing:

5.3.1 Seqirus will remain responsible for the payment to Arcturus of all milestone payments and royalties payable under this Agreement with respect to Net Sales of Vaccine Products made by such Seqirus Affiliates or sublicensees;

5.3.2 Seqirus shall be responsible for failure by its Affiliates and sublicensees to comply with the terms and conditions of this Agreement;

5.3.3 Seqirus shall, within [***] of a grant of a sublicense, notify Arcturus of each sublicense granted to any Third Party, including the identity of such Third Party and the scope of the license granted; and

5.3.4 Unless otherwise agreed between the Parties on a case-by-case basis (e.g., with a view of converting certain sublicenses into direct licenses with Arcturus), all

sublicenses shall automatically terminate (and Seqirus shall ensure that all sublicenses automatically terminate) upon termination (for whatever reason) of the correlative license granted hereunder.

5.4 **Retention of Rights**.

5.4.1 Notwithstanding the exclusive licenses granted to Seqirus pursuant to Section 5.1 (Grants to Seqirus), Arcturus retains:

(i) the right to practice under the Arcturus Patents, the Arcturus Know-How, Regulatory Approvals and any other Regulatory Documentation to perform (and to sublicense Third Parties to perform on Arcturus' behalf) its obligations under this Agreement; and

(ii) the right to practice under the Arcturus Patents and the Arcturus Know-How to perform the Arcturus Ongoing Third-Party Obligations, including the right to grant the licenses and sublicenses required pursuant to the Arcturus Ongoing Third-Party Obligations.

5.4.2 Except as expressly provided herein, Arcturus grants no other right or license, including any rights or licenses to the Arcturus Patents, the Arcturus Know-How, the Regulatory Documentation, the Arcturus Corporate Names, or any other Patent or Intellectual Property rights not otherwise expressly granted herein..

5.4.3 Except as expressly provided herein, Seqirus grants no other right or license, including any rights or licenses to the Seqirus Patents, the Seqirus Know-How, the Regulatory Documentation, or any other Patent or Intellectual Property rights not otherwise expressly granted herein.

5.5 **Confirmatory Patent License**. Arcturus shall, if requested to do so by Seqirus, immediately enter into confirmatory license agreements in the form or substantially the form reasonably requested by Seqirus for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as Seqirus considers appropriate.

5.6 **Exceptions to Seqirus Rights**. Notwithstanding anything to the contrary in this Agreement and the rights granted to Seqirus in Section 5.1 (Grants to Seqirus), the Parties acknowledge the following:

5.6.1 [***].

5.6.2 **BARDA**. Under the Arcturus BARDA Agreement, Arcturus is obligated to conduct certain pre-clinical activities and clinical development activities relating to Phase I Studies with respect to pandemic influenza vaccine candidates. The Parties shall confer with respect to actions and decisions to be taken or made by Arcturus under the Arcturus BARDA Agreement and such actions and decisions shall be taken and made by Arcturus in a manner that (i) complies with the terms and conditions of the Arcturus BARDA Agreement, (ii) preserves and seeks to facilitate the collaboration pursuant to this Agreement in [***] Field with respect to seasonal and pandemic influenza, and (iii) prevents any adverse impact on the

collaboration pursuant to this Agreement. The data and results of activities conducted by Arcturus under the Arcturus BARDA Agreement shall be included in Arcturus Licensed IP for purposes of this Agreement. For avoidance of doubt, the Parties intend that Arcturus shall have the right to fulfill all of its obligations under the BARDA Agreement.

5.6.3 [***].

5.7 **Exclusive Dealing**.

5.7.1 [***]

5.7.2 [***]

5.7.3 [***]

5.7.4 [***]

5.8 **Substitution of** [***] **in the** [***] **Field**.

5.8.1 During the Selection Term, and subject to this Section 5.8, Seqirus may, [***].

5.8.2 If Seqirus wishes to exercise its replacement right under Section 5.8.1, the Parties shall follow the gatekeeping procedure set forth on Schedule 5.8.2 ("**Gatekeeping Procedure**").

5.8.3 If Seqirus determines to [***]

5.9 **Collaboration Know-How; Contributed Background Know-How**.

5.9.1 **Grant to Seqirus**.

(i) Arcturus hereby grants to Seqirus a non-exclusive, irrevocable (subject to Section 12.14.1), perpetual (subject to Section 12.14.1), royalty-bearing (as set forth in Section 6.7) license (which shall be sublicensable solely as set forth in Section 5.9.3) to use any Collaboration Know-How Controlled by Arcturus or Contributed Background Know-How Controlled by Arcturus for [***].

5.9.2 **Grant to Arcturus**. [***].

5.9.3 **Sublicensing**. The licenses set forth in Sections 5.9.1(i) and 5.9.2 shall be sublicensable only (i) to Affiliates, and (ii) to Third Parties solely in connection with a product or candidate developed, designed, discovered or generated in whole or in part by a Party (or its Affiliates). Seqirus will remain responsible for the payment to Arcturus of all royalties payable under Section 6.7 (Royalties for Contributed Background Expanded Know-How License) with respect to net sales of such products, whether made directly by Seqirus or by its Affiliates or sublicensees pursuant to a sublicense granted under this Section 5.9.3.

ARTICLE 6
PAYMENTS AND RECORDS

6.1 **Upfront Payment**. In partial consideration of the rights granted by Arcturus to Seqirus hereunder and subject to the terms and conditions set forth in this Agreement, Seqirus shall pay Arcturus a one- time, nonrefundable upfront amount equal to Two Hundred Million Dollars ($200,000,000) within three (3) Business Days after the Effective Date.

6.2 **Conditional Payment**.

6.2.1 In partial consideration of the rights granted by Arcturus to Seqirus hereunder and subject to the terms and conditions set forth in this Agreement, Seqirus shall pay Arcturus a one-time non-refundable upfront amount of upon the satisfaction of the following events (the "**Condition**" and the "**Conditional Payment**", respectively):

(i) By [***],; and

(ii) By [***].

6.2.2 Arcturus shall promptly notify Seqirus in writing of the achievement of each of the foregoing events, and may invoice Seqirus on or following notice of the achievement of both Conditions. Seqirus shall pay the Conditional Payment within of the receipt of such invoice.

6.3 **Development Milestones**. In partial consideration of the rights granted by Arcturus to Seqirus hereunder and subject to the terms and conditions set forth in this Agreement, during the Payment Term, Seqirus shall pay to Arcturus a milestone payment, calculated as set forth in this Section 6.3 (each, a "**Development Milestone Payment**").

6.3.1 [***] **Field**. The Development Milestone Payments set forth in this Section 6.3.1 shall be (a)(1) with respect to Section 6.3.1(i), in connection with the [***] of the, and (2) with respect to 6.3.1(ii)-(viii), in connection with the completion of, and in each case of (1) and (2) the delivery of, and (b) payable only one time and upon the first achievement of the corresponding milestone event by a Vaccine Candidate or Vaccine Product, and no amounts shall be due for subsequent or repeated achievements of such milestone event for any Vaccine Candidate or Vaccine Product. For clarity, each of the Development Milestone Payments set forth in subsections (ii)-(viii) below is not dependent on [***].

(i) upon [***];

(ii) upon [***];

(iii) upon [***];

(iv) upon [***];

(v) upon [***];

(vi) upon [***];

(vii) upon [***];

(viii) upon[***].; and

(ix) upon [***].

The Development Milestone Payments set forth in this Section 6.3.1 [***] and [***] of the corresponding milestone event by a [***], and no amounts shall be due for [***] of [***] for [***]. Except as otherwise expressly set forth in this Agreement (including Sections 2.1.2(g) and 3.2.2), such milestone payments are non-refundable.

6.3.2 [***] **Field**. Each of the Development Milestone Payments set forth in this Section 6.3.2 shall be nonrefundable, payable only one time and upon the first achievement of the corresponding milestone event by a Vaccine Candidate or Vaccine Product, and no amounts shall be due for subsequent or repeated achievements of such milestone event for any Vaccine Candidate or Vaccine Product:

(i) upon [***];

(ii) upon [***];

(iii) upon [***];

(iv) upon [***];

(v) upon [***];

(vi) upon [***]; and

(vii) upon [***].

6.3.3 [***] **Field**. Each of the Development Milestone Payments set forth in this Section 6.3.3 shall be nonrefundable and payable on a pathogen-by-pathogen basis only one time and upon the first achievement of the corresponding milestone event by a Vaccine Candidate or Vaccine Product, and no amounts shall be due for subsequent or repeated achievements of such milestone for any Vaccine Candidate or Vaccine Product:

(i) upon [***];

(ii) upon [***];

(iii) upon [***]; and

(iv) upon [***].

6.3.4 [***] **Field**. Each of the Development Milestone Payments set forth in this Section 6.3.4 shall be nonrefundable and payable on an basis only one time and upon the

first achievement of the corresponding milestone event with respect to such and no amounts shall be due for subsequent or repeated achievements of such milestone event for any Vaccine Candidate or Vaccine Product for the same or with respect to an alternative pathogen substituted for a prior

(i) upon [***];

(ii) upon [***];

(iii) upon [***];

(iv) upon [***];

(v) upon [***];

(vi) upon [***]; and

(vii) upon [***].

6.4 **Net Sales-Based Milestones**.

6.4.1 In partial consideration of the license rights granted by Arcturus to Seqirus hereunder, subject to Section 6.4.2, during the Payment Term, in the event that the Net Sales of a particular Vaccine Product made by Seqirus or any of its Affiliates or Sublicensees in a given [***] in total exceeds a threshold set forth in the left-hand column of the table immediately below for the first time, Seqirus shall pay to Arcturus a one-time non-refundable milestone payment in the corresponding amount set forth in the right-hand column of the annual Net Sales-based milestone table (each, a "**Net Sales-Based Milestone Payment**").

	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
	[***]	[***]
	[***]	[***]

6.4.2 Notwithstanding anything contained in Section 6.4.1, each Net Sales-based Milestone Payment set forth in this Section 6.4 (Net Sales-Based Milestones) shall be payable only upon the first achievement of the corresponding milestone event in a given [***], and no amounts shall be due for subsequent or repeated achievements of such milestone event in subsequent [***]

6.5 **Gross Profits and Shared Net Profits for** [***] **Field**. The calculation of [***] shall be made in accordance with Schedule **6.5**.

6.5.1 From and after the Effective Date, within [***] after the end of each [***], Arcturus shall provide Seqirus with a written report (each, an "**Arcturus** [***] **Report**") setting forth in reasonable detail [***]. Each [***] shall include [***], as applicable, in [***]. The [***] shall include [***] incurred [***] and [***] for [***], or [***], the [***] Development Plan.

6.5.2 Within [***] after receiving an [***], Seqirus shall provide Arcturus with a written report setting forth in reasonable detail (a) [***], and (b) [***] (each, a "**Seqirus** [***] **Report**"). Each [***] shall include [***], as applicable, in [***]. If there is no [***] in [***], any [***] shall be [***], as applicable, [***] of [***] in [***] in accordance with Schedule 6.5.

6.5.3 Each [***] and each [***] shall specify in reasonable detail [***] during [***] and shall [***]. Each such report shall enable the receiving Party to compare the reported costs against the budgets in the applicable Plan, on [***] and a [***]. With respect to each report, the Parties shall seek to resolve any questions related to such accounting statements within [***] following receipt by the receiving Party of the reporting Party's report hereunder.

6.5.4 If following the procedures set forth in this Section 6.5, there is [***] for [***] for the [***] in the [***], then [***].

6.5.5 For purposes of this Section 6.5 and Schedule 6.5, [***]**.**

6.5.6 [***].

6.6 **Royalties.**

6.6.1 **Royalty Rates**. As further consideration for the rights granted to Seqirus hereunder, subject to Section 6.9 (Royalty and Milestone Reductions for [***] Field, [***] Field and [***] Field), during the Payment Term, commencing upon the First Commercial Sale of a Vaccine Product in a Field other than the [***] Field in the Territory, on a Vaccine Product-by-Vaccine Product basis, Seqirus shall pay to Arcturus a royalty on Net Sales of each Vaccine Product in a Field other than the [***] Field in the Territory during each [***] at the following rates:

(i) [***] **Field.**

a) [***]; and

b) [***],

(ii) [***] **Field.**

a) [***]; and

b) [***].

c) [***].

(iii) [***] **Field.**

a) [***]; and

b) [***].

6.6.2 **Payment Term**. Seqirus shall have no obligation to pay any royalty with respect to Net Sales of any Vaccine Product in any country or other jurisdiction in the Territory after the Payment Term for such Vaccine Product in such country or other jurisdiction has expired.

6.7 **Royalties for Expanded Know-How License**. Upon the First Commercial Sale by Seqirus or its Affiliate or its or their sublicensee pursuant to Section 5.9.3 (Sublicensing) of [***], on a [***], [***] shall (i) notify Arcturus within thirty (30) days of such First Commercial Sale and (ii) pay to Arcturus a royalty on Net Sales of each such product outside the Fields during each Calendar Year at a royalty of [***]. Such calculations (including deductions in the calculation of Net Sales), payment terms and timing shall apply, *mutatis mutandis*, in the same manner as in Sections 6.6, (Royalties), 6.8.3 (Royalty Payments and Reports), 6.10 (Mode of Payment), and 6.17 (Confidentiality). For avoidance of doubt, Section 6.9 (Royalty and Milestone Reductions for Influenza Field, Other Pathogens Field and Pandemic Preparedness Field) shall not apply to this Section 6.7. This Section 6.7 shall terminate on [***].

6.8 **Payment Terms**.

6.8.1 **Development Milestone Payments**. Seqirus shall provide Arcturus with written notice of the achievement of each Development Milestone Payment event by Seqirus, its Affiliate or its or their Sublicensee within [***] after the achievement of the milestone. Following receipt of such notification, Arcturus shall invoice Seqirus for the amount of the applicable Development Milestone Payment, and Seqirus shall make the corresponding Development Milestone Payment within [***] after receipt of such invoice; provided, however, that with respect to [***] for [***], [***].

6.8.2 **Net Sales-Based Milestone Payments**. Seqirus shall provide Arcturus with written notice of the achievement of each Net Sales-Based Milestone Payment event by Seqirus, its Affiliate or its or their Sublicensee within [***] after the financial verification of achievement of the milestone. Following receipt of such notification, Arcturus shall invoice Seqirus for the amount of the applicable Net Sales-Based Milestone Payment, and Seqirus shall make the corresponding Net Sales-Based Milestone Payment(s) within [***] after receipt of such invoice.

6.8.3 **Royalty Payments and Reports**.

(i) Seqirus shall calculate all amounts payable to Arcturus pursuant to Section 6.6 (Royalties) at the end of each [***], which amounts shall be converted to Dollars, in accordance with Section 6.10 (Mode of Payment). Within [***] after the end of each [***], Seqirus shall provide to Arcturus a report containing good faith estimates of the items set forth above and such other information reasonably requested by Arcturus for it to comply with its disclosure obligations under U.S. securities Applicable Laws.

(ii) Within [***] after the end of each [***], Seqirus shall provide to Arcturus a report of the amount of Net Sales of each Vaccine Product in each country or other jurisdiction in the Territory during the applicable [***] (including such amounts expressed in local currency and as converted to Dollars), the calculation of the amount of royalties due on such Net Sales, the aggregate year-to-date Net Sales of each Vaccine Product during the applicable [***] and a calculation of the amount of royalty payment due on such Net Sales for such [***].

(iii) Following receipt of a report from Seqirus in accordance with Section 6.8.3 that indicates a positive amount due to Arcturus for a [***] report, Arcturus shall invoice Seqirus for such amount due, which amount shall be payable [***] after the receipt of a valid invoice.

6.9 **Royalty and Milestone Reductions for** [***] **Field,** [***] **Field and** [***] **Field**. Notwithstanding anything to the contrary in this Agreement, the royalty and milestone payments for Vaccine Products in the [***] Field, [***] Field and [***] Field shall be reduced by the following step-down provisions:

6.9.1 **Payment Floor**. Notwithstanding anything to the contrary in this Agreement, (i) [***], and (ii) [***]. For the avoidance of doubt, any [***] under this Section 6.9 that do not apply because [***] in accordance with this Section 6.9.1 [***].

6.9.2 **Exclusions**. Notwithstanding anything to the contrary in this Agreement, nothing in this Section 6.9 (Royalty and Milestone Reductions for [***] Field, [***] Field and [***] Field) shall reduce (i).

6.9.3 [***]

6.9.4 **Third Party Licenses**.

(i) **Shared FTO Costs**.

a) [***].

b) [***].

(ii) **Other Third Party Licenses**. [***]

(iii) [***] **Field**. [***].

6.9.5 **No Valid Claim**. During the Payment Term, in the event that, and in such case from and after the date on which, [***] in [***], (i) [***], and (ii) [***]with respect to [***], shall [***].

6.10 **Mode of Payment**. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's standard conversion methodology consistent with Accounting Standards. Such standard conversion methodology shall be based upon the Monthly Average Exchange Rate. "**Monthly Average Exchange Rate**" means the simple average of prior month-end Exchange Rate and current month-end Exchange Rate based on 9:00 AM Central Time Bloomberg screen on the penultimate Business Day of the corresponding month, and "**Exchange Rate**" means, with respect to a Business Day, the spot bid rate for X currencies and spot ask rate for non-X currencies for the conversion of the applicable country's or other jurisdiction's currency to Dollars as reported at 9:00 AM Central Time Bloomberg screen on the penultimate Business Day.

6.11 **Accounting Procedures**. For purposes of determining [***] and [***], any [***] by [***] to [***], [***] and [***] shall [***] under [***] or [***], respectively. [***] shall determine [***] and [***] using its standard accounting procedures, consistently applied, to the maximum extent practicable as if [***] were [***]. Each Party shall have the right to audit the other Party's records to confirm the accuracy of the other Party's costs and reports as provided in Section 6.15 (Audit). Transfers between a Party and its Affiliates (or between such Affiliates) shall not have any effect for purposes of calculating [***], [***] or [***] or other payments or expenses under this Agreement.

6.12 **Method of Payment**. All amounts payable and calculations under this Agreement will be in United States Dollars. As applicable, all costs and expenses will be translated into United States Dollars at the exchange rate used by the relevant Party for public financial accounting purposes. Each payment hereunder will be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at the paying Party's election, to such bank account as the receiving Party will designate in writing to the other Party within [***] of the Execution Date or to such other account identified in any invoice. Unless otherwise specified herein, each invoice is payable within [***] of receipt of the relevant invoice. Without limiting any remedy available to any Party, [***], [***], [***].

6.13 **Withholding Taxes**.

6.13.1 **General**. The milestones, royalties and other amounts payable by Seqirus to Arcturus pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Seqirus shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Arcturus is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable

withholding tax, it may deliver to Seqirus or the appropriate governmental authority (with the assistance of Seqirus) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Seqirus of its obligation to withhold such tax and Seqirus shall apply the reduced rate of withholding or dispense with withholding, as the case may be. If, in accordance with the foregoing, Seqirus withholds any amount, it shall pay to Arcturus the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Arcturus proof of such payment within [***] following such payment.

6.13.2 Where any sum due to be paid to either Party hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any relevant domestic tax provisions, or applicable double taxation agreement or treaty. In the event there are no relevant domestic tax provisions, or applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the payor shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to payee and secure and send to payee the best available evidence of such payment.

6.13.3 The Parties agree that no withholding of taxes is currently applicable under Applicable Law. Seqirus shall use Commercially Reasonable Efforts to provide Arcturus with at least [***] prior notice of any obligation to withhold any taxes under Applicable Law. If (i) Seqirus (or its permitted assignee) redomiciles or assigns its rights or obligations under this Agreement, (ii) as a result of such redomiciliation or assignment, Seqirus (or its permitted assignee) is required by Applicable Law to withhold taxes, or if such redomiciliation or assignment results in the imposition of indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes ("**Indirect Taxes**")) that were not otherwise applicable, from or in respect of any amount payable under this Agreement (or any other agreement entered into pursuant to this Agreement), and (iii) such withholding taxes or Indirect Taxes exceed the amount of withholding taxes or Indirect Taxes that would have been applicable if such redomiciliation or assignment had not occurred, then any such amount payable shall be increased to take into account such increased withholding taxes or Indirect Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts) and/or paying such Indirect Taxes, as the case may be, Arcturus (or its permitted assignee) receives an amount equal to the sum it would have received had such redomiciliation or assignment not occurred.

6.14 **Financial Records**. Each Party shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to, as applicable, including books and records of actual expenditures with respect to the budgets set forth in each Plan, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by such Party and its Affiliates until the later of (a) [***] after the end of the period to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

6.15 **Audit**. At the request of the other Party, each Party shall, and shall cause its Affiliates to, permit an independent public accounting firm of internationally recognized standing

designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 6.14 (Financial Records) to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any [***] more than [***] after the end of such [***], (b) be conducted more than once in any [***] period (unless a previous audit during such [***] period revealed an underpayment with respect to such period) or (c) be repeated for any [***]. The accounting firm shall disclose only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [***] from the reported amounts, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 6.16 (Audit Dispute) below, if such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due, or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((i) or (ii)), within [***] after the date on which such audit is completed by the auditing Party.

6.16 **Audit Dispute**. In the event of a dispute with respect to any audit under Section 6.15 (Audit), Arcturus and Seqirus shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Audit Arbitrator**"). The decision of the Audit Arbitrator shall be final and the costs of such arbitration, as well as the initial audit, shall be borne between the Parties in such manner as the Audit Arbitrator shall determine. Not later than [***] after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due, or the auditing Party shall reimburse the excess payments, as applicable.

6.17 **Confidentiality**. The receiving Party shall treat all information subject to review under this ARTICLE 6 in accordance with the confidentiality provisions of ARTICLE 9 (Confidentiality And Non-Disclosure) and the Parties shall cause the Audit Arbitrator to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

6.18 **No Other Compensation**. Each Party hereby agrees that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE 7
INTELLECTUAL PROPERTY

7.1 **Ownership of Intellectual Property**.

7.1.1 **Ownership of Background Intellectual Property**. As between the Parties, (a) Seqirus shall own and retain all right, title, and interest in and to Seqirus' Background IP, and (b) Arcturus shall own and retain all right, title, and interest in and to Arcturus' Background IP. For clarity, Intellectual Property specific to ARCT-021, ARCT-154 and/or ARCT-165, as they exist as of the Execution Date, shall be deemed Arcturus' Background IP.

7.1.2 **Ownership of Foreground IP**.

(i) **Arcturus Foreground IP**. Subject to **[***],** as between the Parties, Arcturus shall own all right, title and interest in and to the Arcturus Foreground IP.

(ii) **Product Specific Foreground IP**. As between the Parties, the Parties shall each own an equal, undivided interest in any and all Product Specific Foreground IP.

(iii) **Seqirus Foreground IP**. As between the Parties, Seqirus shall own all right, title and interest in and to the Seqirus Foreground IP.

(iv) **Seqirus Improvement Foreground IP**. As between the Parties, the Parties shall each own an equal, undivided interest in any and all Seqirus Improvement Foreground IP.

(v) **Other Foreground IP**. Ownership of any Foreground IP that is not Arcturus Foreground IP, Product Specific Foreground IP, Seqirus Foreground IP or Seqirus Improvement Foreground IP ("**Other Foreground IP**") shall follow inventorship.

(vi) [***].

(vii) **United States Law**. The determination of whether Information and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other Intellectual Property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where such conception, discovery, development or making occurs.

(viii) **Assignment Obligation**. Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their licensees and sublicensees to make any assignment necessary to fully effect the ownership provisions of this Section 7.1.2 (Ownership of Foreground IP). Each Party shall cause all Persons who perform Research, Development, or Manufacturing activities for such Party under this Agreement to be under an obligation to assign their rights in any Information and inventions resulting therefrom to such Party.

(ix) **Disclosure Obligation**. Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, licensees and sublicensees to so disclose, the development, making, conception or reduction to practice of any Product Specific Know-How or Product Specific Patents.

7.1.3 **Ownership of Corporate Names**. As between the Parties, each Party shall retain all right, title and interest in and to its Corporate Names.

7.2 **Maintenance and Prosecution of Patents**.

7.2.1 **Patent Prosecution and Maintenance Rights of Seqirus**. Seqirus shall have the right, but not the obligation, to prepare, file, prosecute, and maintain the Seqirus Patents, the Product Specific Patents and Patents directed to Other Foreground IP solely owned by Seqirus (collectively, the "**Seqirus Prosecution Patents**") worldwide, at Seqirus' sole cost and expense. Seqirus shall not include as an essential element of any of its patent applications any non-public Arcturus' Background IP without Arcturus' prior written consent. Seqirus shall periodically inform Arcturus of all material steps with regard to the preparation, filing, prosecution, and maintenance of Product Specific Patents, including by providing Arcturus with a copy of material communications to and from any patent authority regarding such Product Specific Patents. In the event that Seqirus decides not to prepare, file, prosecute, or maintain a Product Specific Patent in a country or other jurisdiction, Seqirus shall provide reasonable prior written notice to Arcturus of such intention (which notice shall, in any event, be given no later than [***] prior to the next deadline for any action that may be taken with respect to such Product Specific Patent in such country or other jurisdiction), and Arcturus shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Product Specific Patent at its expense in such country or other jurisdiction. Upon Arcturus' written acceptance of such option, Arcturus shall assume the responsibility and control for the preparation, filing, prosecution, and maintenance of such specific Product Specific Patent (at which point, it shall be deemed to be an Arcturus Prosecution Patent). In such event, Seqirus shall reasonably cooperate with Arcturus in such country or other jurisdiction as provided under Section 7.2.3 (Cooperation).

7.2.2 **Patent Prosecution and Maintenance Rights of Arcturus** . Arcturus shall have the right, but not the obligation, to prepare, file, prosecute, and maintain the Arcturus Patents that are solely owned by Arcturus, (collectively, the "**Arcturus Prosecution Patents**") worldwide at Arcturus' sole cost and expense. Arcturus shall not include as an essential element of any of its patent applications any non-public Seqirus' Background IP without Seqirus' prior written consent. Arcturus shall periodically inform Seqirus of all material steps with regard to the preparation, filing, prosecution and maintenance of Arcturus Prosecution Patents in the Territory, including by providing Seqirus with a copy of substantive and material communications to and from any patent authority in the Territory regarding Patents directed to Seqirus Improvements and by providing Seqirus drafts of any newly drafted patent applications prior to filing the same. In the event that Arcturus decides not to prosecute or maintain an Arcturus Prosecution Patent in a country or other jurisdiction in the Territory, Arcturus shall provide reasonable prior written notice to Seqirus of such intention (which notice shall, in any event, be given no later than [***] prior to the next deadline for any action that may be taken with respect to such a Patent in such country or other jurisdiction), and, with respect to any Arcturus Prosecution Patent that is solely applicable to the [***] Field, [***] Field, [***] Field or, to the extent exclusively licensed, a pathogen in the [***] Field, Seqirus shall thereupon have the option, in its sole discretion, to assume the control and direction of the prosecution and maintenance of such Arcturus Prosecution Patent (at which point, it shall be deemed to be a Seqirus Prosecution Patent) at its expense in such country or other jurisdiction.

Upon Seqirus' written acceptance of such option, Seqirus shall assume the responsibility and control for the prosecution and maintenance of such a Patent. In such event, Arcturus shall reasonably cooperate with Seqirus in such country or other jurisdiction as provided under Section 7.2.3 (Cooperation).

7.2.3 **Cooperation**. The Parties agree to cooperate fully in the preparation, filing, prosecution, and maintenance of Patents in the Territory under this Agreement as set forth in Section 7.2.1 (Patent Prosecution and Maintenance Rights of Seqirus) and Section 7.2.2 (Patent Prosecution and Maintenance Rights of Arcturus).

7.2.4 **Patent Term Extension and Supplementary Protection Certificate**. Seqirus shall be exclusively responsible for making decisions regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, for Arcturus Patents, Seqirus Patents, and any Product Specific Patents in any country or other jurisdiction. Seqirus shall have the responsibility of applying for any extension or supplementary protection certificate with respect to such Patents in the Territory. Seqirus shall keep Arcturus fully informed of its efforts to obtain such extension or supplementary protection certificate. Arcturus shall provide prompt and reasonable assistance, as requested by Seqirus, including by taking such action as patent holder as is required under any Applicable Law to obtain such patent extension or supplementary protection certificate. Subject to the Gross Profit sharing in the [***] Field, Seqirus shall bear all expenses with respect to obtaining the extension or supplementary protection certificate in the Territory.

7.2.5 **CREATE Act**. Notwithstanding anything to the contrary in this ARTICLE 7, neither Party shall have the right to make an election under the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. 103(c)(2)-(c)(3) (the "**CREATE Act**") when exercising its rights under this ARTICLE 7 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings, or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

7.2.6 **Patent Listings**. Seqirus shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to Arcturus Patents, Seqirus Patents, and Product Specific Patents, including as required or allowed (a) in the United States, in the FDA's Orange Book or Purple Book, and (b) outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents, provided that if Seqirus elects not to pursue such listing for an Arcturus Patent, Arcturus shall have the right, at its own expense, to so list any such Arcturus Patent. Arcturus shall (i) provide to Seqirus all Information, including a correct and complete list of Arcturus Patents covering any Vaccine Product or otherwise necessary or reasonably useful to enable Seqirus to make such filings with Regulatory Authorities in the Territory with respect to such Patents, and (ii) cooperate with Seqirus' reasonable requests in connection therewith, including meeting any submission deadlines, in each case ((i) and (ii)), to the extent required or permitted by Applicable Law.

7.3 **Enforcement of Patents**.

7.3.1 **Enforcement of Patents**. Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of the Seqirus Patents, the Product Specific Patents, the Arcturus Patents or the Patents that cover Seqirus Improvement Foreground IP by a Third Party in the Territory based on the development, manufacturing, commercialization or an application to market by such Third Party of an sa-mRNA or other mRNA vaccine candidate or product within the [***] Field, [***] Field, [***] Field or, to the extent exclusively licensed, a [***] in the [***] Field of which such Party becomes aware (an "**Infringement**"). Seqirus shall have the first right, but not the obligation, to prosecute any such Infringement in the Fields in the Territory at its sole expense and Seqirus shall retain control of the prosecution of such claim, suit or proceeding. In the event Seqirus prosecutes any such Infringement, Arcturus shall have the right to join as a party to such claim, suit or proceeding in the Fields in the Territory and participate with its own counsel at its own expense; provided that Seqirus shall retain control of the prosecution of such claim, suit or proceeding. If Seqirus does not take commercially reasonable steps to prosecute the alleged or threatened Infringement in the Fields in the Territory with respect to such Patents (a) within [***] following the first notice provided above with respect to such alleged Infringement, or (b) provided such date occurs after the first such notice of Infringement is provided, [***] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Arcturus may prosecute the alleged or threatened Infringement in the Fields in the Territory at its own expense.

7.3.2 **Cooperation**. The Parties agree to cooperate fully in any Infringement action pursuant to this Section 7.3 (Enforcement of Patents). Where a Party brings such an action, the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any patent infringement litigation in accordance with Section 7.3 (Enforcement of Patents) shall have the right to settle such claim; provided that neither Party shall have the right to settle any patent infringement litigation under Section 7.3 (Enforcement of Patents) in a manner that diminishes or has a material adverse effect on the rights or interest of the other Party, or in a manner that imposes any costs or liability on, or involves any admission by, the other Party, without the express written consent of such other Party. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court and shall consider reasonable input from the other Party during the course of the proceedings. The Party entitled to bring any patent infringement litigation in accordance with Section 7.3 (Enforcement of Patents) shall be entitled at its own expense and in its absolute discretion, by notice in writing to the other Party, to take such action as is reasonably necessary in the name of and on behalf of the other Party; provided, that, in taking action on the name of or on behalf of the other Party, the prosecuting shall, in good faith, take into account and have due regard to any reputational matters or issues arising out of the claim for the other Party or any of its directors, officers, employees or agents which are brought to its attention by the other Party.

7.3.3 **Recovery**. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 7.3.1 or Section 7.3.2 (whether by way of settlement or otherwise) shall be first,

allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), and any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to bring the enforcement action; provided, that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales or profits with respect to a Vaccine Product in the field in the Territory or results in royalty payments going forward, such remainder shall be allocated to Seqirus and treated as Net Sales.

7.4 **Infringement Claims by Third Parties**. If the manufacture, sale, or use of a Vaccine Candidate or Vaccine Product in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by Seqirus (or its Affiliates or Sublicensees), Seqirus shall promptly notify Arcturus thereof in writing. Seqirus shall have the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense (but subject to the treatment of Shared FTO Costs described in Schedule 6.5 (Gross Profits and Shared Net Profits for SARS-CoV-2 Field) or Section 6.9.4(i) (Shared FTO Costs), as the case may be), using counsel of its own choice. Arcturus may participate in any such claim, suit, or proceeding with counsel of its choice at its own expense (and such expenses shall not be considered Shared FTO Costs). Without limitation of the foregoing, if Seqirus finds it necessary or desirable to join Arcturus as a party to any such action, Arcturus shall execute all papers and perform such acts as shall be reasonably required. Seqirus shall keep Arcturus reasonably informed of all material developments in connection with any such claim, suit, or proceeding.

7.5 **Product Trademarks**.

7.5.1 **Ownership and Prosecution of Product Trademarks**. all right, title, and interest to the Product Trademarks worldwide, and shall be responsible for the registration, prosecution, and maintenance thereof. All costs and expenses of registering, prosecuting, and maintaining the Product Trademarks shall be borne solely by. shall provide all assistance and documents reasonably requested by in support of its prosecution, registration, and maintenance of the Product Trademarks.

7.5.2 **Enforcement of Product Trademarks**. shall have the sole right and responsibility for taking such action as, deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party worldwide. shall bear the costs and expenses relating to any enforcement action commenced pursuant to this Section 7.5.2 (Enforcement of Product Trademarks) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

7.5.3 **Third Party Claims**. shall have the sole right and responsibility for defending against any alleged, threatened, or actual claim by a Third Party that the use or registration of the Product Trademarks worldwide infringes, dilutes, misappropriates, or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Vaccine

Product worldwide. shall bear the costs and expenses relating to any defense commenced pursuant to this Section 7.5.3 (Third Party Claims) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

7.5.4 **Notice and Cooperation**. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks worldwide and of any actual or threatened claim that the use of the Product Trademarks worldwide violates the rights of any Third Party. Each Party agrees to cooperate fully with the other Party with respect to any enforcement action or defense commenced pursuant to this Section 7.5 (Product Trademarks).

7.6 **Inventor's Remuneration**. Each Party shall be solely responsible for any remuneration that may be due such Party's inventors under any applicable inventor remuneration laws.

ARTICLE 8
QUALITY, PHARMACOVIGILANCE AND SAFETY

8.1 **Quality**. Within [***] from [***], the Parties shall enter into a quality agreement that shall set forth in detail the quality assurance arrangements and procedures with respect to the Research, Development, Manufacturing and supply of the Vaccine Products, reporting customer complaints, conducting timely investigations, recalls, logistics (including warehousing and shipping requirements) and testing requirements. Such quality agreement shall be incorporated herein as Schedule 8.1 by reference following execution by both Parties.

8.2 **Pharmacovigilance**. Within [***] after [***], the Parties shall enter into an agreement to initiate a process for the exchange of safety data relating to Vaccine Candidates and Vaccine Products (including any post-marketing spontaneous reports received by each Party and its Affiliates) in a mutually agreed format in order to monitor the safety of the Vaccine Candidates or Vaccine Products and to meet reporting requirements with any applicable Regulatory Authority. Such pharmacovigilance agreement shall be incorporated herein as Schedule 8.2 by reference following execution by both Parties. .

8.3 **Global Safety Database**. The pharmacovigilance agreement under Section 8.2 (Pharmacovigilance) shall provide the terms and conditions under which the Parties will exchange safety-related data in order to comply with their respective pharmacovigilance responsibilities. with all information necessary or desirable for to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any safety-related or adverse drug experiences, from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, and Clinical Studies with a Vaccine Candidate or Vaccine Product or the Arcturus Technology platform, reported anywhere in the world, in each case in the form and manner reasonably requested and further specified in the pharmacovigilance agreement. In addition, with respect to any Clinical Trial Applications/Investigational New Drug Applications or Drug Approval Applications that may be maintained by Arcturus or its partners, Arcturus with all information necessary or desirable for Arcturus to comply with its pharmacovigilance responsibilities, including, as applicable, any adverse drug experiences, from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, Clinical Studies, and commercial

experiences, in each case to the extent in' possession and control and in the form reasonably requested by Arcturus and further specified in the pharmacovigilance agreement..

ARTICLE 9
CONFIDENTIALITY AND NON-DISCLOSURE

9.1 **Product Information**. Arcturus recognizes that by reason of, *inter alia*, Seqirus' status as an exclusive licensee pursuant to the grants under Section 5.1 (Grants to Seqirus), Seqirus has an interest in Arcturus' maintaining the confidentiality of certain information of Arcturus. Accordingly, during the Term, Arcturus shall, and shall direct its controlled Affiliates and its and their respective officers, directors, employees, and agents to, keep confidential, and not publish or otherwise disclose any Confidential Information Controlled by Arcturus or any of its Affiliates relating exclusively to (x) any Vaccine Candidate or Vaccine Product (for which Seqirus is an exclusive licensee under Section 5.1 (Grants to Seqirus)) for use in the Fields in the Territory, or (y) the Exploitation of any of the foregoing in the Field in the Territory (the "**Product Information**"); except to the extent (a) the Product Information is in the public domain through no fault of Arcturus, its Affiliates or any of its or their respective officers, directors, employees, or agents; (b) such disclosure is expressly permitted under Section 9.3 (Permitted Disclosures), or (c) such disclosure is otherwise expressly permitted by the terms of this Agreement. Solely for purposes of Section 9.3 (Permitted Disclosures), Seqirus shall be deemed to be the disclosing Party with respect to Product Information under Section 9.3 (Permitted Disclosures) and Arcturus shall be deemed to be the receiving Party with respect thereto. For further clarification, (i) without limiting this Section 9.1 (Product Information), to the extent Product Information is disclosed by Arcturus to Seqirus pursuant to this Agreement, such information shall, subject to the other terms and conditions of this ARTICLE 9 (Confidentiality And Non-Disclosure), also constitute Confidential Information of Arcturus with respect to the use and disclosure of such Information by Arcturus (and Arcturus shall be deemed to be the disclosing Party with respect to Product Information under Section 9.3 (Permitted Disclosures) and Seqirus shall be deemed to be the receiving Party with respect thereto), but (ii) the disclosure by Arcturus to Seqirus of Product Information shall not cause such information to cease to be subject to the provisions of this Section 9.1 (Product Information) with respect to the use and disclosure of such Confidential Information by Arcturus. In the event this Agreement is terminated in its entirety or with respect to a Terminated Field or Terminated Other Pathogen, this Section 9.1 (Product Information) shall have no continuing force or effect with respect to the use or disclosure of such information solely in connection with the Exploitation of the Vaccine Candidates or Vaccine Products in connection with such Terminated Field or Terminated Other Pathogen.

9.2 **Confidentiality Obligations**.

9.2.1 At all times during the Term and (x) with respect to any Confidential Information that is a trade secret under United States Law, for so long as such Confidential Information retains the status of a trade secret under United States Law and (y) for all other Confidential Information, for a period of [***] following termination or expiration hereof in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure

or use is expressly permitted by the terms of this Agreement. Notwithstanding the foregoing, to the extent the receiving Party can be demonstrate by documentation or other competent proof, the confidentiality and non-use obligations under this Section 9.2 (Confidentiality Obligations) with respect to any Confidential Information shall not include any information that:

(i) has been published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

(ii) has been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information; provided that the foregoing exception shall not apply with respect to Regulatory Documentation or Product Specific Know-How;

(iii) is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party;

(iv) that is generally made available to Third Parties by the disclosing Party without restriction on disclosure; or

(v) has been independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information; provided that the foregoing exception shall not apply with respect to Regulatory Documentation or Product Specific Know-How.

9.2.2 Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

9.3 **Permitted Disclosures**. Each Party may disclose Confidential Information to the extent that such disclosure is:

9.3.1 in the reasonable opinion of the receiving Party's outside legal counsel, required to be disclosed pursuant to law, regulation or a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction, (including by reason of filing with securities regulators, but subject to Section 9.5 (Public Announcements)); provided, that, unless prohibited by Applicable Law, the receiving Party shall first have given prompt written notice (and to the extent possible, at least [***] notice) to the disclosing Party and given the disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information (for example, quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such

order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued). The receiving party will use its commercially reasonable efforts to cooperate with the disclosing party to obtain any relief, at the sole expense of the disclosing party. In the event that no protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Agreement, the receiving Party shall furnish only that portion of Confidential Information which the receiving Party is advised by counsel is legally required to be disclosed;

9.3.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval under, and in accordance with the terms of, this Agreement; provided, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with Applicable Law;

9.3.3 made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining, defending or enforcing a Patent under, and in accordance with the terms of, this Agreement; provided, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information, to the extent such protection is available;

9.3.4 made to its or its Affiliates' financial and legal advisors who have a need to know such disclosing Party's Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, in each case, at least as restrictive as those set forth in this Agreement; provided that the receiving Party shall remain responsible for any failure by such financial and legal advisors, to treat such Confidential Information as required under this Article;

9.3.5 made by Seqirus or its Affiliates or Sublicensees to its or their advisors, consultants, clinicians, vendors, service providers, contractors, existing or prospective collaboration partners, licensees, sublicensees, or other similar Third Parties as may be necessary or useful in connection with the performance of its obligations or exercise of its rights as contemplated by, and in accordance with the terms of, this Agreement; provided, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this ARTICLE 9 (Confidentiality And Non-Disclosure) (with a duration of confidentiality and non-use obligations as appropriate that is no less than [***] from the date of disclosure for advisors, consultants, clinicians, vendors, service providers, contractors and no termination period for trade secrets for so long as they maintain their treatment as trade secrets under Applicable Law); or

9.3.6 made by Arcturus or its Affiliates, to its or their advisors, consultants, clinicians, vendors, service providers, contractors existing or prospective collaboration partners, licensees, sublicensees or other Third Parties as may be, necessary or useful in performing its obligations or exercising its rights as contemplated by, and in accordance with the terms of, this Agreement; provided, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information of

Seqirus substantially similar to the obligations of confidentiality and non-use of Arcturus pursuant to this ARTICLE 9 (Confidentiality And Non-Disclosure) (with a duration of confidentiality and non-use obligations as appropriate that is no less than [***] from the date of disclosure and no termination period for trade secrets for so long as they maintain their treatment as trade secrets under United States Law).

9.4 **Use of Name**. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 9.4 (Use of Name) shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law; provided, that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party at least [***] prior to the anticipated date of disclosure so as to provide a reasonable opportunity to comment thereon.

9.5 **Public Announcements**. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for the press release(s) in the form(s) attached hereto as Schedule 9.5. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and if permitted under Applicable Law, not less than [***] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. The publishing Party will incorporate the other Party's reasonable comments into its publication. Notwithstanding the foregoing, each Party and its and their respective Affiliates shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Vaccine Candidates and Vaccine Products in the Fields other than Confidential Information of the other Party. Nothing in this Section 9.5 shall prohibit a Party or its Affiliates from including any information in a public announcement, press release, or other public disclosure regarding this Agreement or its subject matter which has already been disclosed in a public announcement, press release, or other public disclosure made by a Party in compliance with this Section 9.5.

9.6 **Publications**. The Parties acknowledge that scientific publications must be strictly monitored to prevent any adverse effect from premature publication of results of the Research or Development or Commercialization activities hereunder. Accordingly:

9.6.1 Without limiting any other obligations of Arcturus under this Agreement, Arcturus shall not publish, present, or otherwise disclose, and shall cause its Affiliates and Third Party Providers and its and their employees and agents not to disclose any Confidential Information of Seqirus without the prior written consent of Seqirus. Consequently, if Arcturus wishes to make a publication containing Confidential Information of Seqirus (which for purposes of this Section 9.6.1 shall include Product Information), it shall deliver to Seqirus a copy of the proposed written publication at [***] prior to its submission. Seqirus shall have the right (a) to propose modifications to the publication for patent reasons, trade secret reasons

or business reasons and/or (b) to request a reasonable submission delay in order to protect patentable information. If Seqirus requests such a delay, Arcturus shall delay the submission to enable patent applications protecting Seqirus' rights in such Information to be filed in accordance with ARTICLE 7. If Seqirus requests modifications to the publication, Arcturus shall edit such publication to prevent disclosure of trade secret or other proprietary business information of Seqirus prior to its submission; and

9.6.2 Without limiting any other obligations of Seqirus under this Agreement, Seqirus shall not publish, present, or otherwise disclose, and shall cause its Affiliates and Third Party Providers and its and their employees and agents not to disclose any Confidential Information of Arcturus without the prior written approval by Arcturus. Consequently, if Seqirus wishes to make a publication containing Confidential Information of Arcturus, it shall deliver to Arcturus a copy of the proposed written publication at least [***] prior to its submission. Arcturus shall have the right (a) to propose modifications to the publication for patent reasons or trade secret reasons, and/or (b) to request a reasonable submission delay in order to protect patentable information. If Arcturus requests such a delay, Seqirus shall delay the submission to enable patent applications protecting Arcturus' rights in such Information to be filed in accordance with ARTICLE 7. If Arcturus requests modifications to the publication, Seqirus shall edit such publication to prevent disclosure of trade secret information of Arcturus prior to its submission.

9.7 **Return of Confidential Information**. Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information (in the event of termination of this Agreement with respect to one (1) or more Terminated Fields or Terminated Other Pathogens, but not in its entirety, solely to the extent relating specifically and exclusively to such Terminated Fields or Terminated Other Pathogens, as applicable) to which such first Party does not retain rights under the surviving provisions of this Agreement: (a) as soon as reasonably practicable, destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) as soon as reasonably practicable, deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, that the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder, as required by Applicable Law, or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

9.8 **Survival**. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 9.2 (Confidentiality Obligations).

ARTICLE 10
REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 **Mutual Representations and Warranties**. Arcturus and Seqirus each represents and warrants to the other, as of the Execution Date, and covenants, as follows:

10.1.1 **Organization** . It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

10.1.2 **Authorization** . The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

10.1.3 **Binding Agreement**. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

10.1.4 **No Inconsistent Obligation.** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

10.2 **Additional Representations and Warranties of Arcturus**. Subject to the disclosures set forth in disclosure schedules of Arcturus delivered with the execution of this Agreement, Arcturus further represents and warrants to Seqirus, as of the Execution Date, and covenants, as follows:

10.2.1 **Existing Patents**. All Arcturus Patents in the Fields existing as of the Execution Date are listed on Schedule 10.2.1 (the "**Existing Patents**"). All Existing Patents are, to the extent issued, subsisting and, to Arcturus' Knowledge, are not invalid or unenforceable, in whole or in part.

10.2.2 [***]

10.2.3 The execution and delivery of this Agreement, the exercise of the Parties' respective rights and the performance of the Parties' respective obligations hereunder do not and will not conflict with, violate, breach, trigger payment

obligations, or constitute a default under [***], any [***] or [***]. [***] is not an Affiliate of [***].

(i) Arcturus shall not [***].

(ii) Arcturus has made available to Seqirus all unredacted portions of the [***], [***], [***], [***], and [***] that relate to [***]. None of the Intellectual Property arising under this Agreement will be transferred, licensed or otherwise shared by Arcturus with any such Third Parties in a manner in conflict with the licenses granted under this Agreement.

(iii) As of the Execution Date, Arcturus has entered into the [***] and continues to be a party to [***], under which Arcturus, along with [***], shall continue to conduct the activities that are the subject of [***], as well as ongoing [***], [***] for [***], and related activities, and shall in each such case use [***] .

(iv) [***] .

10.2.4 Arcturus is (a) the sole and exclusive owner of the entire right, title and interest in the Existing Patents listed on Schedule 10.2.1, Part A (the "**Owned Patents**") and (b) the sole and exclusive licensee of the Existing Patents listed on Schedule 10.2.1, Part B (the "**In-Licensed Patents**"), in each case ((a) and (b)) free of any encumbrance, lien, or, claim of ownership by any Third Party. Arcturus is entitled to grant the licenses specified herein. All the agreements related to the In-Licensed Patents are listed on Schedule 10.2.1, Part C (the "**In-Licensed Agreements**"). True, complete, and correct copies (which may be redacted) of the In-Licensed Agreements have been provided or made available to Seqirus prior to the Execution Date. As of the Effective Date, none of Arcturus, its Affiliates, and, to Arcturus' Knowledge, any Third Party is in breach of any In-Licensed Agreement.

10.2.5 Arcturus has the right to use all Information and Patents Controlled by Arcturus and, to its Knowledge, all other Information and Patents necessary to conduct its activities under the Research Activities.

10.2.6 During the Term, neither Arcturus nor any of its Affiliates shall encumber or diminish the rights granted to Seqirus hereunder with respect to the Arcturus Patents.

10.2.7 True, complete, and correct copies of: (a) the file wrapper of non-published Existing Patents; (b) all Existing Regulatory Documentation requested by Seqirus; and (c) all material adverse information with respect to the safety and efficacy of the Vaccine Candidates known to Arcturus, in each case ((a) through (c)) have been provided or made available to Seqirus prior to the Execution Date.

10.2.8 In respect of the pending patent applications included in the Existing Patents, Arcturus and its Affiliates have presented all relevant references, documents, or information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office in accordance with Applicable Laws.

10.2.9 The Existing Patents represent all Patents owned or controlled by Arcturus or its Affiliates (i) relating to the Vaccine Candidates or the Vaccine Products in the Fields, or (ii) otherwise necessary or useful for the activities contemplated by this Agreement, as of the Execution Date.

10.2.10 Arcturus and its Affiliates have generated, prepared, maintained, and retained all Regulatory Documentation that is required to be maintained or retained pursuant to and in accordance with GLP and GCP and Applicable Law, and all such information is true, complete and correct and what it purports to be.

10.2.11 Each officer, employee, agent, or consultant of Arcturus who has or has had any rights in or to any Existing Patents or any Arcturus Know-How, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Existing Patents and Arcturus Know-How to Arcturus. To Arcturus' Knowledge, no current officer, employee, agent, or consultant of Arcturus or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other Intellectual Property or proprietary information of Arcturus or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Arcturus.

10.2.12 All works of authorship and all other materials subject to copyright protection included in Arcturus Know-How are original and were either created by employees of Arcturus or its Affiliates within the scope of their employment or are otherwise works made for hire, or all right, title, and interest in and to such materials have been legally assigned and transferred to Arcturus or such Affiliate, and all rights in all inventions and discoveries, made, developed, or conceived by any employee or independent contractor of Arcturus or any of its Affiliates during the course of their employment (or other retention) by Arcturus or such Affiliate, and relating to or included in Arcturus Know-How or that are the subject of one (1) or more Existing Patents have been or will be assigned in writing to Arcturus or such Affiliate.

10.2.13 The Arcturus Know-How has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality. To the Knowledge of Arcturus, no breach of such confidentiality has been committed by any Third Party.

10.2.14 [***]

10.2.15 Neither Arcturus, nor any of its Affiliates or its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the Vaccine Candidates or the Vaccine Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the Vaccine Candidates or the Vaccine Products, or committed an act, made a statement, or failed to make a statement with respect to the Development of the Vaccine Candidates or the Vaccine Products that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

10.2.16 Arcturus, its Affiliates and their respective contractors and consultants have conducted all Research and Development of the Vaccine Candidates or the Vaccine Products in the Fields that they have conducted prior to the Execution Date in accordance with Applicable Law, and to the extent required, in accordance with GLP and GCP. Arcturus has conducted, and has caused its contractors and consultants to conduct, any and all pre-clinical and Clinical Studies (if any) related to the Vaccine Candidates and Vaccine Products in the Fields in accordance with GLP and, with respect to Clinical Studies, GCP and Applicable Law. Arcturus and its Affiliates have employed Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical and Clinical Studies with respect to the Vaccine Candidates and Vaccine Products.

10.2.17 Arcturus and, to Arcturus's knowledge, its employees, agents, subcontractors or consultants performing hereunder, have not been, are not currently, or are not the subject of a proceeding that would reasonably be expected to lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. If, during the Term, Arcturus, or any of its employees, agents, subcontractors or consultants performing hereunder, become or are the subject of a proceeding that would reasonably be expected to lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, Arcturus shall promptly notify Seqirus, and, if such status will have, or would be deemed by a reasonable person knowledgeable in the industry to have, a material adverse impact on Seqirus' interest in this Agreement, then Seqirus shall have the right to terminate this Agreement. This provision shall survive termination or expiration of this Agreement. For purposes of this provision, the following definitions shall apply:

(i) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.

(ii) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(iii) An "Excluded Individual" or "Excluded Entity" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(iv) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

10.3 **Additional Representations and Warranties of Seqirus**. Seqirus further represents and warrants to Arcturus, as of the Execution Date, and covenants, as follows:

10.3.2 Seqirus and, to Seqirus' knowledge, none of its employees or agents performing hereunder, have not been, are not currently, or are not the subject of a proceeding that would reasonably be expected to lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. If, during the Term, Seqirus, or any of its employees or agents performing hereunder, become or are the subject of a proceeding that would reasonably be expected to lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, Seqirus shall promptly notify Arcturus. This provision shall survive termination or expiration of this Agreement.

10.3.3 The execution and delivery of this Agreement and the performance of the Parties' respective obligations hereunder do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of Seqirus or any of its Affiliates existing as of the Execution Date.

10.3.4 Seqirus has the right to use all Information and Patents necessary to conduct its activities under the Research Activities.

10.4 **Covenants of Arcturus**. Arcturus covenants as follows:

10.4.1 At such times as reasonably requested by Seqirus following the Effective Date, Arcturus shall [***]

10.4.2 Except for Information that is in the public domain, neither Arcturus nor its Affiliates shall enter into any agreement that would divest from Arcturus or its Affiliates Control of Patents or, to Arcturus' Knowledge at the time of divestiture, Information that is necessary to enable Seqirus (or its designees) to Exploit the Vaccine Candidates or the Vaccine Products in the Fields in the Territory as set forth in this Agreement.

10.4.3 During the Term, neither Arcturus nor any of its Affiliates shall encumber the Arcturus Patents in a manner that would have the effect of preventing Seqirus from exercising the rights and licenses granted in this Agreement.

10.4.4 During the Term, Arcturus shall not **[***]**

10.4.5 Arcturus shall perform its obligations, and use [***] to [***], under [***] in a diligent manner intended to facilitate [***] and shall keep Seqirus fully informed and updated with respect thereto, including by promptly notifying Seqirus of any reports or notices from [***] thereunder.

10.5 **Covenants of the Parties**. Each Party covenants as follows:

10.5.1 **No Obligation to Divest**. Notwithstanding any other provision of this Agreement, in no event shall either Party be required to undertake or enter into any agreement, consent decree or other commitment requiring either Party to divest, lease, license, transfer, sell, dispose of, encumber (including through the granting of any license rights) or hold separate any businesses, product lines, or assets or to take any other action that would have an adverse effect on the business, assets, properties, liabilities, condition (financial or otherwise), operating results, operations or prospects of either Party.

10.5.2 **No Obligation To Litigate**. Notwithstanding any other provision of this Agreement, and except as set forth in ARTICLE 7, in no event shall either Party be required to participate in any court claim or suit by any governmental entity or other Person commenced which questions the validity or legality of the transactions contemplated by this Agreement or seeks damages in connection therewith.

10.5.3 **Directing Antitrust Strategy**. Seqirus shall have the right to control and direct the process, strategy and determinations by which the Parties seek to avoid or eliminate impediments that may exist, arise or be asserted under any antitrust law in connection with this Agreement or the transactions contemplated hereunder; provided that Seqirus shall first consult with Arcturus prior to taking any related action and shall keep Arcturus apprised of the status of matters relating to antitrust law.

10.6 **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

10.7 **Covenant Prior to Effective Date**. Each Party covenants to the other Party that, from the Execution Date through the Effective Date, such Party shall not willfully and knowingly take any action or omit to take any action if, as a result of such action or omission, any of the representations and warranties of such Party stated in this Article 10 would be untrue or inaccurate as of the Effective Date.

ARTICLE 11
INDEMNITY

11.1 **Indemnification of Arcturus**. Seqirus shall indemnify Arcturus, its Affiliates and its and their respective directors, officers, employees, and agents (the "**Arcturus Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") incurred by or rendered against the Arcturus Indemnitees arising from or occurring as a result of:

(a) the breach by Seqirus of this Agreement; or

(b) the negligence or willful misconduct on the part of Seqirus or its Affiliates or their respective directors, officers, employees, and agents in performing its or their obligations under this Agreement; or

(c) [***];

except in the case of clauses (a), (b) and (c), for those Losses for which Arcturus, in whole or in part, has an obligation to indemnify Seqirus pursuant to Section 11.2 (Indemnification of Seqirus) hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

11.2 **Indemnification of Seqirus**. Arcturus shall indemnify Seqirus, its Affiliates and its and their respective directors, officers, employees, and agents (the "**Seqirus Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred by or rendered against the Seqirus Indemnitees arising from or occurring as a result of:

(a) the breach by Arcturus of this Agreement; or

(b) the negligence or willful misconduct on the part of Arcturus or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Agreement;

except, in the case of clauses (a) through (b) above for those Losses for which Seqirus, in whole or in part, has an obligation to indemnify Arcturus pursuant to Section 11.1 (Indemnification of Arcturus) hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

11.3 **Notice of Claim**. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this ARTICLE 11, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

11.4 **Control of Defense**.

11.4.1 **General** . Subject to the provisions of Section 7.4 (Infringement Claims by Third Parties) and Section 7.5 (Product Trademarks), at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] after the indemnifying Party's receipt of an

Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party which shall be reasonably acceptable to the Indemnified Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 11.4.2, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

11.4.2 **Right to Participate in Defense**. Without limiting Section 11.4.1, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 11.4.1 (in which case the Indemnified Party shall control the defense), or (c) in the opinion of outside counsel to the Indemnified Party, the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

11.4.3 **Settlement**. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.4.1, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided, that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party

Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the indemnifying Party, which consent shall not to be unreasonably withheld, conditioned or delayed. The indemnifying Party shall not be liable for any settlement, compromise or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed.

11.4.4 **Cooperation** . Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

11.4.5 **Expenses** . Except for [***], the reasonable and verifiable costs and expenses, including reasonable fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a [***] basis in [***] by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

11.5 **Special, Indirect, and Other Losses**. EXCEPT (A) FOR WILLFUL MISCONDUCT, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 9 (CONFIDENTIALITY AND NON-DISCLOSURE), (C) AS PROVIDED UNDER SECTION 13.10 (EQUITABLE RELIEF), AND (D) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 11 (INDEMNITY), NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF THE VACCINE CANDIDATES OR VACCINE PRODUCTS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

11.6 **Insurance**. Each Party shall have and maintain such type and amounts of insurance covering its obligations under this Agreement and the Supply Agreement as is (a) normal and customary in the pharmaceutical industry generally for parties similarly situated and (b) otherwise required by Applicable Law.

ARTICLE 12
TERM AND TERMINATION

12.1 **Term**.

12.1.1 **HSR and Other Governmental Filings** . The Parties shall each, as soon as practicable after the Execution Date, file or cause to be filed with the U.S. Federal Trade Commission and the U.S. Department of Justice and any relevant foreign governmental authority any notifications required to be filed under the HSR Act (the "**HSR Filing**") or any similar applicable foreign law or regulation with respect to the transactions contemplated hereby; provided that the Parties shall each make the HSR Filing within [***] after the Execution Date and shall each file any notifications or filings required to be filed under similar applicable foreign laws and regulations as promptly as reasonably practicable. The Parties shall use their commercially reasonable efforts to respond promptly to any requests for additional information made by such agencies..

12.1.2 **Term**. Notwithstanding anything in this Agreement to the contrary, this Agreement (other than Sections 5.6.3 (), 10.7 (Covenant Prior to Effective Date) and 12.1.1 (HSR and Other Governmental Filings), this Section 12.1.2 (Term), and Section 12.3 (), which are binding and effective as of the Execution Date) shall not become effective until the expiration or earlier termination of the waiting period (or any extension thereof) under the HSR Act in the United States (the date of such expiration or earlier termination, the "**Effective Date**"), and upon the Effective Date the full Agreement and all its terms and provisions shall be automatically effective and binding on both Parties. If, on the [***] after the date of filing under the HSR Act the waiting period required thereunder has not expired, either Party shall have the right, on written notice to the other Party, to terminate this Agreement, and upon receipt of such notice by such other Party, this Agreement shall be null and void and have no further force and effect. For clarity, any nullification of this Agreement shall not have any effect on the Confidential Disclosure Agreement between the Parties or their Affiliates dated February 28, 2022 and amended on May 2, 2022, which shall continue to apply with respect to information exchanged between the Parties. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect on a Field-by-Field basis until the date of expiration of the last Payment Term for the last Vaccine Product in such Field (such period on a Field-by-Field basis, the "**Field Term**", and through the date of the last Field Term, the "**Term**").

12.1.3 **Effect of Expiration**. For clarity, references to the expiration of this Agreement, a Field Term, or the Term mean the expiration but not the early termination of, respectively, this Agreement, Field Term or the Term. Following the expiration of a Field Term, the grants in Section 5.1 (Grants to Seqirus) shall become fully-paid, royalty-free, perpetual and irrevocable with respect to such Field. [***] Notwithstanding the foregoing, the licenses granted in this Section 12.1.3 (Effect of Expiration) shall apply solely to Intellectual Property as it exists on the date of expiration of the Term. This Section 12.1.3 (Effect of Expiration) shall survive the expiration (but not termination) of this Agreement.

12.2 **Termination for Material Breach**. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") has materially breached one (1) or

more of its material obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a "**Default Notice**"), which Default Notice shall contain a detailed description of the material breach. If the Breaching Party fails to cure such breach within [***] after receipt of the Default Notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party on a Field-by-Field basis, or on an Other Pathogen-by-Other Pathogen basis.

12.3 **Termination** . shall have the right, on written notice to within [***] of the public announcement of the, to terminate this Agreement, and upon receipt of such termination notice from, this Agreement shall be null and void and have no further force and effect (provided for clarity, that the Confidential Disclosure Agreement between the Parties or their Affiliates dated February 28, 2022 and amended on May 2, 2022 shall continue to apply with respect to information exchanged between the Parties).

12.4 **Termination by Seqirus For Convenience**. Seqirus may terminate this Agreement in its entirety, on a Field-by-Field basis, or on an Other Pathogen-by-Other Pathogen basis, for any or no reason, after the Effective Date, upon [***] prior written notice to Arcturus. Notwithstanding the foregoing, Seqirus may not terminate this Agreement in its entirety or with respect to the [***] Field pursuant to this Section 12.4 prior to the First Commercial Sale of a Vaccine Product (other than in the) in [***] or [***]; provided, however, that if prior to such date, then Seqirus may exercise such rights to terminate this Agreement in its entirety or with respect to the [***] Field pursuant to this Section 12.4 by providing notice of such termination prior to the date that is [***] after such. This Section 12.4 shall survive the termination of this Agreement pursuant to this Section 12.4.

12.5 **Additional Termination Rights by Seqirus**.

12.5.1 **For Safety Reasons** . Seqirus shall have the right, on a Vaccine Candidate/Vaccine Product-by-Vaccine Candidate/Vaccine Product basis, to terminate this Agreement at any time upon providing [***] prior written notice to Arcturus: [***]. Any dispute regarding the applicability of this Section 12.5.1 to any Vaccine Candidate or Vaccine Product shall be resolved pursuant to Section 13.6 (Dispute Resolution). Such notice shall set forth Seqirus' analysis in reasonable detail supporting its judgment and its right to terminate this Agreement pursuant to this Section 12.5.1. The last three sentences of this Section 12.5.1 shall survive the termination of this Agreement pursuant to this Section 12.5.1.

12.5.2 **For Clinical Data Nonviability** . Seqirus may terminate this Agreement in its entirety, on a, if [***]. Any dispute regarding the applicability of this Section 12.5.2 to any Vaccine Candidate or Vaccine Product shall be resolved pursuant to Section 13.6 (Dispute Resolution). The last two sentences of this Section 12.5.2 shall survive the termination of this Agreement pursuant to this Section 12.5.2.

12.5.3 **For Commercial Nonviability**. Seqirus may terminate this Agreement in its entirety, on a, upon [***] prior written notice to Arcturus in the event that [***]. Any dispute regarding the applicability of this Section 12.5.3 to any Vaccine Candidate or Vaccine Product shall be resolved pursuant to Section 13.6 (Dispute Resolution). The last

two sentences of this Section 12.5.3 shall survive the termination of this Agreement pursuant to this Section 12.5.3.

12.5.4 **For Regulatory Debarment**. Seqirus may terminate this Agreement in its entirety in accordance with Section 10.2.17 by giving Arcturus written notice of termination referring to Section 10.2.17; provided that such notice of termination shall only be valid if given within [***] of the date of Arcturus' notice to Seqirus under Section 10.2.17.

12.6 **Termination of an Other Pathogen**.

12.6.1 If [***] publicly announces the development of a [***], then [***]shall have the right, on written notice to [***]within [***] of notice from [***]regarding such announcement or otherwise becoming aware of such public announcement, to terminate this Agreement with respect to [***].

12.6.2 Arcturus shall have the right to terminate this Agreement with respect to [***] pursuant to Section 3.1.3 (Diligence Obligations).

12.7 **Termination for Insolvency**. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [***] of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

12.8 **Rights in Bankruptcy**.

12.8.1 **Applicability of 11 U .S.C. § 365(n)**. All rights and licenses granted under or pursuant to this Agreement, including all rights and licenses to use improvements or enhancements developed during the Term, are intended to be, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "**Bankruptcy Code**") or any analogous provisions in any other country or jurisdiction, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that the licensee of such Intellectual Property under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, including Section 365(n) of the Bankruptcy Code, or any analogous provisions in any other country or jurisdiction. All of the rights granted to either Party under this Agreement shall be deemed to exist immediately before the occurrence of any bankruptcy case in which the other Party is the debtor. The Parties acknowledge and agree that the payments provided for under ARTICLE 6 and all other payments by Seqirus to Arcturus hereunder, other than royalty payments pursuant to Section 6.6, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. Nothing in this Agreement limits a Party's rights under Section 365(n) of the Bankruptcy Code

or any other analogous law. No Party by way of this Agreement is presently making an election under Section 365(n) of the Bankruptcy Code or any other analogous.

12.8.2 **Rights of non-Debtor Party in Bankruptcy** . In any bankruptcy case under the Bankruptcy Code or other comparable proceeding under any analogous law in any other country or jurisdiction by or against a Party (in any capacity, including as debtor-in-possession, and any successors or assigns, including any bankruptcy trustee or equivalent, a "debtor Party"), the debtor Party will perform this Agreement unless and until the debtor Party rejects this Agreement under Section 365 of the Bankruptcy Code or takes a comparable act under analogous law. In any such case or proceeding, (a) pending rejection of this Agreement under Section 365 of the Bankruptcy Code or comparable act under analogous law by the debtor Party or (b) upon such rejection or act by the debtor Party and the non-debtor Party thereafter electing to retain its rights under this Agreement pursuant to Section 365(n) of the Bankruptcy Code or other analogous law, the debtor Party shall provide the non-debtor Party, and the non-debtor Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any Intellectual Property and all embodiments of such Intellectual Property, and the debtor Party hereby agrees to grant and hereby grants to the non-debtor Party and its Affiliates a right to access and to obtain possession of and to benefit from and, in the case of any chemical or biological material or other tangible item of which there is a fixed or limited quantity, to obtain a pro rata portion of, each of the following to the extent related to any Vaccine Candidate or Vaccine Product, or otherwise related to any right or license granted under or pursuant to this Agreement: (i) copies of pre-clinical and clinical research data and results; (ii) all of the following (to the extent that any of the following are so related): cell lines, antibodies, assays, reagents and other biological materials; (iii) samples or Vaccine Candidates and Vaccine Products; (iv) Arcturus Licensed IP (if Arcturus is the debtor Party), (v) laboratory notes and notebooks; (vi) Vaccine Candidates and Vaccine Products data or filings, and (vii) rights of reference in respect of filings for and Regulatory Approvals, all of which (inclusive of clauses (i) through (vii)) constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code, and (viii) all other embodiments of such intellectual property, whether any of the foregoing are in the debtor Party's possession or control or in the possession and control of any Third Party but which the debtor Party has the right to access or benefit from and to make available to the non-debtor Party. The debtor Party will not interfere with the exercise by the non-debtor Party or its Affiliates of rights and licenses to Intellectual Property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use Commercially Reasonable Efforts to assist the non-debtor Party and its Affiliates to obtain such Intellectual Property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or useful for the non-debtor Party or its Affiliates or Sublicensees to exercise such rights and licenses in accordance with this Agreement.

12.9 **Effects of Termination in Entirety**. In the event of any termination of this Agreement in its entirety, except to the extent set forth in Section 12.14 (Accrued Rights; Surviving Obligations) (a) all rights and licenses granted by Arcturus hereunder shall immediately terminate; and (b) all rights and licenses granted by Seqirus hereunder shall immediately terminate.

12.10 **Effects of Termination of Terminated Field**.

12.10.1 In the event of a termination of this Agreement with respect to a Field by Seqirus, "Field" shall automatically and immediately be deemed to exclude such Terminated Field. Upon effectiveness of the termination of this Agreement with respect to a Field, Seqirus shall immediately cease using Arcturus Licensed IP with respect to the Terminated Field, and cease Development and Commercialization of any Terminated Product, in the Terminated Field (except as expressly set forth in Section 12.14).

12.10.2 Upon termination of this Agreement with respect to a Field (whether through termination of this Agreement in its entirety or just with respect to the Field), by Arcturus under Section 12.2 or Seqirus under Sections 12.4, 12.5.1, 12.5.2, or 12.5.3, Seqirus shall pay for all Research costs or Development costs (other than those described in the provisions below) incurred by Arcturus or irrevocably committed to by Arcturus in accordance with any applicable Research Plan in the Terminated Field or with respect to the Terminated Product (in the case of a [***]), in each case prior to the date that the terminating Party notifies the other Party of its election to terminate this Agreement; provided, in addition with respect to a termination of [***], (a) [***] (to the extent [***]), (2) [***] (to the extent [***]) and (3) [***] either [***] or [***] to by [***] ([***]), in each case prior to the date the terminating Party notifies the other Party of its election to terminate this Agreement in its entirety or in the [***] Field. All such payments shall be promptly agreed between the Parties and made within [***] from receipt of invoice after election to terminate this Agreement.

12.11 **Effects of Termination with respect to a Terminated Product or Terminated Other Pathogen**. In the event of termination of this Agreement with respect to a Terminated Product or a Terminated Other Pathogen (but not in the case of any termination of this Agreement in its entirety), except to the extent set forth in Section 12.14 (Accrued Rights; Surviving Obligations) (a) all rights and licenses granted by Arcturus to Seqirus hereunder shall automatically be deemed to be amended to exclude, if applicable, the rights with respect to such Terminated Product or Terminated Other Pathogen, as applicable, and (b) all diligence and other obligations of Seqirus and all obligations Arcturus with respect to such Terminated Product or Terminated Other Pathogen, as applicable, shall cease. Upon effectiveness of the termination of this Agreement with respect to a Terminated Product or Terminated Other Pathogen, Seqirus shall immediately cease using Arcturus Licensed IP with respect to or in any Terminated Other Pathogen, and cease Development and Commercialization of any such Terminated Product.

12.12 **Post-Termination Negotiations**. Except if Seqirus terminates this Agreement in accordance with Section 12.2 (Termination for Material Breach), the Parties agree to negotiate in good faith for the grant of (a) a license to Arcturus to use any [***], in each case, as was incorporated into a Vaccine Candidate or Vaccine Product in the Fields as of the date of the termination, and any [***], and (b) access to any Regulatory Approvals and Regulatory Data existing at the time of such termination, as reasonably required for the sole purpose of developing, manufacturing and commercializing in the Terminated Field(s) a Vaccine Candidate or Vaccine Product that is in existence at the time of termination. Except if Arcturus terminates this Agreement in accordance with Section 12.2 (Termination for Material Breach), the Parties agree to negotiate in good faith for the grant of a non-exclusive license to Seqirus to use any [***] in the Terminated Fields. This Section 12.12 shall survive the termination of this Agreement in its entirety or with respect to a Terminated Field, except in the event of a termination by Seqirus in accordance with Section 12.2 (Termination for Material Breach).

12.13 **Remedies**. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more Fields or one (1) or more Vaccine Products) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

12.14 **Accrued Rights; Surviving Obligations**.

12.14.1 Termination or expiration of this Agreement (either in its entirety or with respect to one (1) or more Fields, one (1) or more Other Pathogens, or one (1) or more Vaccine Products) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration, including any rights of a Party under Section 3.6 (Research and Development Costs) and ARTICLE 6 (Payments and Records). Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. This Section 12.14.1 and ARTICLE 9 (Confidentiality and Non-Disclosure) shall survive the expiration or the termination of this Agreement for any reason. Without limiting the foregoing, the following Sections and Articles of this Agreement and the definitions of all defined terms used therein shall survive the expiration or the termination of this Agreement for any reason other than termination by Seqirus pursuant to Section 12.3 (Termination Upon Execution of Agreement to Effect Change of Control of Arcturus) indefinitely, or if a period is specified, for the period set forth below:

(i) The last sentence of Section 3.1.6 (Materials Transfer - disclaimer);

(ii) 3.6.1 (Responsibility for Costs Relating to Research and Development Activities in the [***] Field, [***] Field and [***] Field), with respect to costs reasonably incurred with respect to the winding down of activities conducted by Arcturus pursuant to this Agreement;

(iii) 3.6.2 (Responsibility for Funding Costs Relating to Research and Development Activities in the [***] Field), with respect to costs reasonably incurred with respect to the winding down of activities conducted by Arcturus pursuant to this Agreement;

(iv) 3.6.4 (FTE Costs) with respect to activities chargeable or otherwise to be accounted for under this Agreement;

(v) 5.3.4 [*Non-survival of sublicenses granted under Section 5.1*];

(vi) 5.4 (Retention of Rights);

(vii) 5.7.3 [***];

(viii) 5.9 (Collaboration Know-How; Contributed Background Know-How);

(ix) 7.1.1 (Ownership of Background Intellectual Property)

(x) 7.1.2 (Ownership of Foreground IP), except for Section 7.1.2(ix) (Disclosure Obligation);

(xi) 7.6 (Inventor's Remuneration);

(xii) ARTICLE 8 (Quality, Pharmacovigilance and Safety), during Seqirus' sell-off period pursuant to Section 12.14.3 and for such additional time as required in connection with either Party's legal and regulatory obligations;

(xiii) 11.1 (Indemnification of Arcturus);

(xiv) 11.2 (Indemnification of Seqirus);

(xv) 11.3 (Notice of Claim);

(xvi) 11.4 (Control of Defense);

(xvii) 11.5 (Special, Indirect, and Other Losses);

(xviii) 12.1.2 (Term);

(xix) 12.13 (Remedies);

(xx) 12.14.3 [*Sell-off right*];

(xxi) 12.14.4 [*Patent prosecution transition*]; and

(xxii) ARTICLE 13 (Miscellaneous), except for Sections 13.2 (Export Control), 13.12 (Further Assurances), and 13.15 (Non-Solicitation).

If this Agreement is terminated with respect to the Terminated Field, Terminated Product, or Terminated Other Pathogen, but not in its entirety, then following such termination, the foregoing provisions of this Agreement shall remain in effect with respect to the Terminated Field Terminated Product, or Terminated Other Pathogen, as applicable (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Field, Terminated Product, or Terminated Other Pathogen, as applicable, and be of no further force and effect (and, for purposes of clarity, all provisions of this Agreement shall remain in effect with respect to all countries in the Territory other than the Terminated Field, Terminated Product, or Terminated Other Pathogen).

12.14.2 If Seqirus terminates this Agreement in accordance with Section 12.4 (Termination by Seqirus For Convenience) or if Arcturus terminates this Agreement in accordance with Section 12.2 (Termination for Material Breach), the obligations of Seqirus in Section 5.7 (Exclusive Dealing) to the extent then in effect shall continue for a period of [***] after the effective date of such termination. This Section 12.14.2 shall survive the termination of this Agreement Section 12.4 (Termination by Seqirus For Convenience) or if

Arcturus terminates this Agreement in accordance with Section 12.2 (Termination for Material Breach).

12.14.3 Notwithstanding the termination of Seqirus' licenses and other rights under this Agreement, Seqirus shall have the right for [***] after the effective date of such termination to sell or otherwise dispose of all Vaccine Candidates or Vaccine Products then in its inventory and any in-progress inventory, as though this Agreement had not terminated, and such sale or disposition shall not constitute infringement of Arcturus' or its Affiliates' Patent or other Intellectual Property or other proprietary rights. For purposes of clarity, Seqirus shall continue to make payments thereon as provided in ARTICLE 6 (as if this Agreement had not terminated with respect to such Field). Upon the expiration of such [***] sell-off period for any Terminated Product, Seqirus shall immediately stop selling or otherwise Exploiting such Terminated Product, and shall cause its Affiliates and its and their sublicensees and distributors to do the same.

12.14.4 Notwithstanding the foregoing, in the event of any termination of this Agreement, or any Field, Other Pathogen or Vaccine Product, the Parties shall in good faith discuss and conduct transition of relevant patent prosecution activities and rights to Arcturus, including all Patents in Arcturus Licensed IP that are owned solely or jointly by Arcturus that are primarily applicable to the Terminated Field, Terminated Pathogen or Terminated Other Product, as the case may be. Seqirus will cooperate with Arcturus and provide Arcturus with reasonable assistance and cooperation with the prosecution, maintenance, and enforcement activities with respect to such Arcturus patent rights and joint patent rights.

12.15 **Additional Obligations for Terminated Products**. In the event of any termination of this Agreement by Arcturus pursuant to this Article 12 or by Seqirus pursuant to Section 12.4 (Termination by Seqirus For Convenience) with respect to the Terminated Products (whether pursuant to termination of this Agreement in its entirety, or termination of a Field, Other Pathogen or Vaccine Product), the Parties shall negotiate in good faith the establishment of a transition and wind-down plan that will include a plan with respect to ongoing Clinical Studies, existing Regulatory Documentation and Regulatory Approvals pertaining to the Terminated Products, remaining quantities of the Terminated Products then in Seqirus' possession or control, Product Trademarks that pertain to the Terminated Products, and any other Intellectual Property and Confidential Information that are necessary or are used as of the effective date of such termination to Exploit the Terminated Products. Except if this Agreement is terminated by Arcturus pursuant to Section 12.2 (Termination for Material Breach), and excluding [***] [***]. This Section 12.15 shall survive the termination of this Agreement pursuant to Section 12.4 (Termination by Seqirus For Convenience) or if Arcturus terminates this Agreement in accordance with Section 12.2 (Termination for Material Breach); provided that Seqirus' obligation to pay Arcturus' reasonable out of pocket wind down costs shall survive the termination of this Agreement for any reason.

ARTICLE 13
MISCELLANEOUS

13.1 **Force Majeure**. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in

fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). For clarity, Seqirus operates a pandemic preparedness business and the occurrence of a pandemic may result in a court order or a contractual obligation with a governmental authority to mobilize its resources and as such will be considered a force majeure event to the extent that such mobilization of resources results in an inability to perform obligations under this Agreement. The non-performing Party shall notify the other Party of such force majeure within [***] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

13.2 **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

13.3 **Assignment**.

13.3.1 Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, that (i) Seqirus may make such an assignment without Arcturus's consent to its Affiliate or in connection with the disposition of all or substantially all of the assets to which this Agreement relates and (ii) Arcturus may make such an assign without Seqirus' consent to an entity that acquires all or substantially all of its assets or business. Any attempted assignment or delegation in violation of this Section 13.3 (Assignment) shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Arcturus or Seqirus, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement. Without limiting the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of Arcturus, and the obligations of Seqirus, including the payment obligations, shall run in favor of any such successor or permitted assignee of Arcturus' benefits under this Agreement.

13.4 **Severability**. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

13.5 **Governing Law**. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, that all questions concerning the construction or effect of Patents shall be determined in accordance with the laws of the country or other jurisdiction in which the particular Patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

13.6 **Dispute Resolution**. Except for disputes resolved by the procedures set forth in Section 2.2.3 (Dispute Resolution), Section 6.16 (Audit Dispute) or Section 13.10 (Equitable Relief), if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), it shall be resolved pursuant to this Section 13.6 (Dispute Resolution).

13.6.1 **General**. Any Dispute shall first be referred to the Senior Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within [***] (or such other period of time as mutually agreed by the Senior Officers) after such issue was first referred to them, then, either Party may, by written notice to the other Party, elect to initiate an arbitration proceeding pursuant to the procedures set forth in Section 13.6.2 for purposes of having the matter settled.

13.6.2 **ICC Arbitration** . Subject to Section 13.6.1, any dispute arising out of this Agreement shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce in effect at the time of submitting for arbitration, which rules are deemed to be incorporated by reference in this clause. The arbitration tribunal shall consist of three arbitrators who are experienced in the biopharmaceutical industry. Each Party shall designate one arbitrator and the third arbitrator, who shall serve as chair of the arbitration tribunal, shall be designated by the two party-appointed arbitrators in consultation with the Parties. The seat of arbitration shall be New York, New York, and the arbitration proceedings shall be held in English. The award of the arbitration tribunal shall be final and

judgment upon such an award may be entered in any competent court or application may be made to any competent court for juridical acceptance of such an award and order of enforcement. The costs of the Tribunal shall be paid by the non-prevailing Party. Neither Party or its Affiliates nor any arbitrator may disclose the existence, content, or results of any arbitration under this Agreement without the prior written consent of the applicable parties, unless and only to the extent such disclosure is necessary to confirm, vacate or enforce the award or is otherwise required by Applicable Law. The arbitration tribunal shall not have the power to grant any award or remedy other than such awards or remedies that are available under the governing law set forth in Section 13.5 (Governing Law).

13.6.3 **Adverse Ruling** . Any determination pursuant to this Section 13.6 (Dispute Resolution) that a Party is in material breach of its material obligations hereunder shall specify a (nonexclusive) set of actions to be taken to cure such material breach, if feasible.

13.6.4 **Interim Relief and Tolling**. Notwithstanding anything herein to the contrary, nothing in this Section 13.6 (Dispute Resolution) shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party. This Section shall be specifically enforceable.

13.7 **Notices**.

13.7.1 **Notice Requirements** . Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed to have been duly given on the date delivered, if delivered personally, or on the next Business Day after being sent by reputable international overnight courier (with delivery tracking provided, signature required and delivery prepaid), or by electronic mail upon successful transmission so long as the recipient personally (i.e., not by automated machine response) confirms receipt, in each case, to the address specified in Section 13.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 13.7.1. A copy, which does not constitute notice, may be sent by email.

13.7.2 **Address for Notice**.

If to Seqirus, to:

[***]

If to Arcturus, to:

[***]
Attention: [***]

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

[***]

13.8 **Entire Agreement; Amendments**. This Agreement, the Supply Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including that certain Confidential Disclosure Agreement between the Parties or their respective Affiliates dated February 28, 2022 and amended on May 2, 2022). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.9 **English Language**. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

13.10 **Equitable Relief**. Each Party acknowledges and agrees that the restrictions set forth in Section 5.7 (Exclusive Dealing), ARTICLE 7 (Intellectual Property) and ARTICLE 9 (Confidentiality And Non-Disclosure) are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to obtain or to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 13.10 is intended, or should be construed, to limit either Party’s right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

13.11 **Waiver and Non-Exclusion of Remedies**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do

not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

13.12 **Further Assurance**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.13 **Relationship of the Parties**. It is expressly agreed that Arcturus, on the one hand, and Seqirus, on the other hand, shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency. Neither Arcturus, on the one hand, nor Seqirus, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

13.14 **Performance by Affiliates**. Seqirus may use one (1) or more of its Affiliates to perform its obligations and duties hereunder and such Seqirus' Affiliates are expressly granted certain rights herein; provided that each such Affiliate shall be bound by the corresponding obligations of Seqirus and, subject to an assignment to such Affiliate pursuant to Section 13.3 (Assignment), Seqirus shall remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

13.15 **Non-Solicitation**. During the Term, each Party agrees that it will not, directly or indirectly, induce or solicit any employee of the other Party to terminate his or her employment with such Party; provided, however, that each Party will not be prohibited from discussing employment with any such individual (i) whose employment was terminated by a Party prior to such discussions, (ii) who responds to a general solicitation of employment not targeted specifically at any employees of a Party, (iii) who contacts a Party independently without any solicitation by or on behalf of such Party, and (iv) who has left their employment with a Party prior to any solicitation by or on behalf of a Party.

13.16 **Counterparts; Facsimile Execution**. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

13.17 **References**. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently

amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

13.18 **Schedules**. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

13.19 **Construction**. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean "including, but not limited to," and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

[SIGNATURE PAGE FOLLOWS.**]**

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Execution Date.

ARCTURUS THERAPEUTICS, INC.

By:

Name: Joseph E. Payne

Title: Presidnet and CEO

SEQIRUS, INC.

By:

Name: Dave Sehgal

Title: President

SEQIRUS, INC.

By:

Name: Melissa Puryear

Title: Secretary

[Signature Page to Collaboration and License Agreement]

Schedule 1.30
Arcturus Technology (Partial Listing)

[***]

Schedule 1.55
Corporate Names

[***]

Schedule 1.85
FTE Rates

[***]

Schedule 1.127
Pandemic Preparedness Field

[***]

Schedule 3.1.1
Research Plans

[***]

Schedule 3.1.3
Specific Diligence Milestones for

[***]

Schedule 3.2.1

[***]

Schedule 4.5

STARR and LUNAR Trademarks

[***]

Schedule 4.9
Principal Terms of Supply Agreement

[***]

Schedule 4.10

Manufacturing Technology Transfer Plan

[***]

Schedule 5.8.2

Gatekeeping Procedure (Substitution of Other Pathogen)

[***]

Schedule 6.5
Calculation of Shared Net Profits

[***]

Schedule 8.1
Quality Agreement

[***]

Schedule 8.2
Pharmacovigilance Agreement

[***]

Schedule 9.5
Form of Press Releases

(A) Arcturus Press Release

Arcturus Announces Collaboration with CSL to Develop and Commercialize Self-amplifying mRNA Vaccines

Arcturus to receive upfront payment of $200 million and more than $4 billion in potential development and commercial milestones

40% profit sharing for COVID-19 vaccines, up to double digit royalties for influenza, pandemic preparedness and three additional respiratory infectious disease vaccines

Combines Arcturus' self-amplifying mRNA vaccine technologies with CSL's world-leading capabilities as a commercial scale manufacturer and global distributor of influenza and pandemic vaccines

San Diego, Calif, November 1, 2022 – Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases, today announced a strategic collaboration with CSL Seqirus, a global vaccine leader, for the research, development, manufacture, and global commercialization of vaccines. CSL Seqirus' vaccine portfolio includes the world's second largest influenza vaccine franchise. CSL Seqirus is part of CSL Limited (ASX:CSL; USOTC:CSLLY).

Under the terms of the agreement, Arcturus will provide CSL Seqirus with a license to their self-amplifying mRNA technology to support the research, development, manufacture, and commercialization of vaccines for SARS-CoV-2 (COVID-19), influenza, pandemic preparedness, as well as three other globally prevalent respiratory infectious diseases.

The collaboration combines CSL Seqirus' established global vaccine commercial and manufacturing infrastructure with Arcturus' manufacturing expertise and innovative STARR™ self-amplifying mRNA vaccine and LUNAR® delivery platform technologies. Arcturus will bring its mRNA design and modification expertise, LUNAR® lipid nanoparticle (LNP) technology and manufacturing know-how, which has enabled the Company's low dose, lyophilized and durable self-amplifying mRNA vaccines against COVID-19. Previously reported clinical results from ongoing ARCT-154 studies have demonstrated a favorable efficacy and safety profile with sustained neutralizing antibodies against COVID-19, including recent variants of concern.

"We are excited to embark on this collaboration with CSL Seqirus, a respected world leader in the development, manufacture and commercialization of vaccines," said Joseph Payne, President and CEO of Arcturus Therapeutics. "We look forward to a long and fruitful partnership as we work together to develop next generation self-amplifying mRNA vaccines to protect against the most prevalent infectious diseases."

Summary of Deal Terms and Financial Considerations
Under the terms of the agreement, Arcturus will provide CSL Seqirus with a license to its STARR™ self-amplifying mRNA technology, LUNAR® lipid-mediated delivery, along with

mRNA drug substance and drug product manufacturing expertise. CSL Seqirus will lead development and commercialization of vaccines under the collaboration. The collaboration plans to advance vaccines against SARS-CoV-2 (COVID-19), influenza, pandemic preparedness as well as three other globally prevalent respiratory infectious diseases.

Arcturus will receive $200 million upfront and is eligible to receive over $1.3 billion in development milestones and over $3 billion in commercial milestones. In addition, the Company is eligible to receive a 40% net profit share for COVID-19 vaccine products and up to double-digit royalties for vaccines against flu, pandemic preparedness and three other respiratory pathogens.

J.P. Morgan Securities LLC acted as financial advisor to Arcturus on the transaction.

About Arcturus Therapeutics
Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a global, late-stage clinical mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology (samRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic and vaccine candidates includes mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat ornithine transcarbamylase (OTC) deficiency, and cystic fibrosis, along with partnered programs including glycogen storage disease type III, and hepatitis B virus. Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, replicon RNA, antisense RNA, microRNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (patents and patent applications issued in the U.S., Europe, Japan, China and other countries). Arcturus' commitment to the development of novel RNA therapeutics has led to collaborations including, amongst others, Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., and the Cystic Fibrosis Foundation. more information visit www.ArcturusRx.com. In addition, please connect with us on Twitter and LinkedIn.

About CSL
CSL (ASX:CSL; USOTC:CSLLY) is a leading global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, vaccines to prevent influenza, and therapies in iron deficiency, dialysis and nephrology. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL – including our three businesses, CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 30,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For inspiring stories about the promise of biotechnology, visit CSLBehring.com/Vita and follow us on Twitter.com/CSL. For more information about CSL, visit www.CSL.com.

About CSL Seqirus
CSL Seqirus is part of CSL Limited (ASX: CSL). As one of the largest influenza vaccine providers in the world, CSL Seqirus is a major contributor to the prevention of influenza globally and a transcontinental partner in pandemic preparedness. With state-of-the-art production facilities in

the U.S., the U.K. and Australia, and leading R&D capabilities, CSL Seqirus utilizes egg, cell and adjuvant technologies to offer a broad portfolio of differentiated influenza vaccines in more than 20 countries around the world. For more information about CSL Seqirus, visit www.seqirus.com.

Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact included in this press release, are forward-looking statements, including those regarding strategy, the expectations for or likelihood of success of the collaboration with CSL Sequirus or any collaborations, the likelihood of success of the Company's efforts to design and develop a vaccine against COVID, influenza or any other infectious disease, the strength or potential of the Company's platform, the future activities under and effectiveness of the collaboration, and the impact of general business and economic conditions. Arcturus may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in any forward-looking statements such as the foregoing and you should not place undue reliance on such forward-looking statements. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements, including those discussed under the heading "Risk Factors" in Arcturus' most recent Annual Report on Form 10-K, and in subsequent filings with, or submissions to, the SEC, which are available on the SEC's website at www.sec.gov. Except as otherwise required by law, Arcturus disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

Trademark Acknowledgements

The Arcturus logo and other trademarks of Arcturus appearing in this announcement, including LUNAR® and STARR™, are the property of Arcturus. All other trademarks, services marks, and trade names in this announcement are the property of their respective owners.

IR and Media Contacts

Arcturus Therapeutics
IR@ArcturusRx.com

Kendall Investor Relations
Carlo Tanzi, Ph.D.
(617) 914-0008
ctanzi@kendallir.com

(B) Seqirus Press Release (ASX)

CSL Enters Licensing Agreement with Arcturus Therapeutics for Next Generation mRNA Vaccine Technology

CSL Limited (ASX:CSL; USOTC:CSLLY) today announces that its subsidiary, CSL Seqirus, has entered into a collaboration and license agreement with Arcturus Therapeutics Holdings Inc ("Arcturus Therapeutics") to access their late stage self-amplifying mRNA vaccine platform technology.

Arcturus Therapeutics (NASDAQ: ARCT) is currently developing next generation mRNA vaccines, including a COVID-19 vaccine candidate that recently reported results from a large Phase III vaccine efficacy study, meeting its primary and secondary endpoints of prevention of infection and severe disease with a favourable safety and tolerability profile.

"This collaboration is an exciting opportunity to complement CSL's own next generation mRNA program with a partner who developed a platform to deliver late stage clinical supplies at scale. These combined capabilities will accelerate our journey in mRNA," said CSL Chief Operating Officer Paul McKenzie.

Steve Marlow, CSL Seqirus General Manager, added "Importantly, it is another step towards our long-term aim to advance public health by developing and commercialising enhanced vaccines for influenza and multi-pathogen pandemic preparedness. The collaboration also provides a pathway to offer a COVID-19 booster, providing another differentiated option to healthcare providers and governments around the world."

Under the agreement, CSL will have the exclusive licence to Arcturus' next generation mRNA technology in the fields of influenza, COVID-19, and other respiratory viral diseases, and a non-exclusive license in the multi-pathogen pandemic preparedness field with the right to turn exclusive. Arcturus will receive an upfront payment of US$200 million and will be eligible to receive further payments dependent upon the achievement of certain development and commercial milestones along with royalties/profit sharing on future product sales.

CSL's Head of R&D and Chief Medical Officer, Dr Bill Mezzanotte said "This collaboration on next generation mRNA is another example of CSL's relentless pursuit of disruptive innovation when public health and patients can benefit. We look forward to working with Arcturus to shape the future therapeutic landscape of influenza vaccines and also using this exciting scientific and strategic platform to develop and commercialize vaccines for other seasonal and pandemic respiratory viruses with high unmet need."

The transaction is subject to customary regulatory clearances before closing.

Authorised for lodgement by:

Fiona Mead
Company Secretary

For further information, please contact:

Investors:	**Media:**
Bernard Ronchi	**Jimmy Baker**
Investor Relations	CSL Financial Communications
P: +613 9389 3470	P: +61 450 909 211
E: bernard.ronchi@csl.com.au	E: jimmy.baker@csl.com.au

Seqirus Press Release (NASDAQ)

CSL Enters Licensing Agreement with Arcturus Therapeutics for Next Generation mRNA Vaccine Technology

King of Prussia, PA – [Date] – CSL Limited (ASX:CSL; USOTC:CSLLY) today announces that its subsidiary, CSL Seqirus, has entered into a collaboration and license agreement with Arcturus Therapeutics Holdings Inc ("Arcturus Therapeutics") to access their late stage self-amplifying mRNA (sa-mRNA) vaccine platform technology.

Arcturus Therapeutics (NASDAQ: ARCT) is currently developing next generation mRNA vaccines. It has developed a COVID-19 vaccine candidate and has recently reported results from a large Phase III vaccine efficacy study, meeting its primary and secondary endpoints of prevention of infection and severe disease with a favorable safety and tolerability profile.

"This collaboration is an exciting opportunity to complement CSL's own next generation mRNA program with a partner who developed a platform to deliver late stage clinical supplies at scale. These combined capabilities will accelerate our journey in mRNA," said CSL Chief Operating Officer Paul McKenzie.

Steve Marlow, CSL Seqirus General Manager, added "Importantly, it is another step towards our long-term aim to advance public health by developing and commercializing enhanced vaccines for influenza and multi-pathogen pandemic preparedness. The collaboration also provides a pathway to offer a COVID-19 booster, providing another differentiated option to healthcare providers and governments around the world."

CSL Seqirus is a global leader in influenza prevention and has a longstanding heritage in influenza vaccines. This along with CSL R&D's established capabilities in vaccine research and clinical development, positions CSL well to make strategic investments in both the development of the company's existing platforms and in longer-term, high opportunity development activities.

CSL Seqirus produces influenza vaccines across its global manufacturing network, which includes facilities in the U.S., U.K. and Australia. CSL also continues to grow its R&D footprint and is investing in a new facility located in Waltham, Mass. that will support the company's R&D portfolio, with a focus on the sa-mRNA technology platform. This facility will serve as an R&D

center for current and future vaccine design, and collaborations with stakeholders from across industry and academia.

CSL's Head of R&D and Chief Medical Officer, Dr Bill Mezzanotte said, "This collaboration on next generation mRNA is another example of CSL's relentless pursuit of disruptive innovation when public health and patients can benefit. We look forward to working closely with Arcturus to shape the future therapeutic landscape of influenza vaccines and also using this exciting scientific and strategic platform to develop and commercialize vaccines for other seasonal and pandemic respiratory viruses with high unmet need."

About COVID-19

COVID-19 is a disease caused by a virus named SARS-CoV-2 and is highly contagious. COVID-19 may cause respiratory symptoms – ranging from mild symptoms to life threatening severe illness. Symptoms may appear 2-14 days after exposure to the virus. During the COVID-19 pandemic, there have been over 95 million confirmed cases of the disease and over 1 million deaths in the United States. The Centers for Disease Control and Prevention (CDC) recommend COVID-19 vaccination for everyone ages 6 months and older in the United States for the prevention of COVID-19. It is recommended to stay up-to-date on COVID-19 vaccination by completing a primary series vaccination and receiving the most recent booster dose recommended for them by the CDC.

About Seasonal Influenza

Influenza is a common, contagious seasonal respiratory disease that may cause severe illness and life-threatening complications in some people. Influenza can lead to clinical symptoms varying from mild to moderate respiratory illness to severe complications, hospitalization and in some cases, death. Because transmission of influenza viruses to others may occur one day before symptoms develop and up to 5 to 7 days after becoming sick, the disease can be easily transmitted to others. Estimates from the CDC report that during the 2019/20 influenza season, there were an estimated 405,000 influenza-related hospitalizations in the U.S. The CDC recommends annual vaccination for individuals aged 6 months and older, who do not have any contraindications. Since it takes about two weeks after vaccination for antibodies to develop in the body that help protect against influenza virus infection, it is recommended that people get vaccinated before influenza

begins spreading in their community. The CDC recommends that people get vaccinated by the end of October.

About Pandemic Influenza

Pandemic influenza, is a contagious airborne respiratory disease which is unpredictable in timing and severity. The risk of influenza-associated morbidity and mortality is greater with pandemic influenza than with seasonal influenza because there is likely to be little or no pre-existing immunity to the virus in the human population. Four influenza pandemics have occurred over the past century, with the 1918 pandemic being the most severe in recent history, estimated to have killed up to 50 million people worldwide. According to the CDC, a novel influenza A virus such as the highly pathogenic avian A(H5N1) strain can cause severe disease and have a high mortality rate. If the influenza A(H5N1) virus were to change and become easily transmissible from person to person while retaining its capacity to cause severe disease, the consequences for public health could be severe.

About CSL

CSL (ASX:CSL; USOTC:CSLLY) is a leading global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat hemophilia and immune deficiencies, vaccines to prevent influenza, and therapies in iron deficiency, dialysis and nephrology. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL – including our three businesses, CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 30,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For inspiring stories about the promise of biotechnology, visit CSLBehring.com/*Vita* and follow us on Twitter.com/CSL.
For more information about CSL, visit www.CSL.com.

About CSL Seqirus

CSL Seqirus is part of CSL Limited (ASX: CSL). As one of the largest influenza vaccine providers in the world, CSL Seqirus is a major contributor to the prevention of influenza globally and a transcontinental partner in pandemic preparedness. With state-of-the-art production facilities in

the U.S., the U.K. and Australia, and leading R&D capabilities, CSL Seqirus utilizes egg, cell and adjuvant technologies to offer a broad portfolio of differentiated influenza vaccines in more than 20 countries around the world. For more information about CSL Seqirus, visit www.seqirus.com.

# # #

Media Contact

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Email: Greg.Healy@cslbehring.com

CSL Seqirus Communications
Polina Miklush
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CSL Financial Communications
Jimmy Baker
Mobile: +61 450 909 211
Email: Jimmy.Baker@csl.com.au

Schedule 10.2.1

[***]

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Joseph E. Payne, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcturus Therapeutics Holdings 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 9, 2022

By: /s/ Joseph E. Payne

Joseph E. Payne
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Andy Sassine, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcturus Therapeutics Holdings 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 9, 2022

By: /s/ Andy Sassine

Andy Sassine
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, the President and Chief Executive Officer of Arcturus Therapeutics Holdings Inc. (the "Company"), hereby certifies on the date hereof, pursuant to 18 U.S.C. 1350(a), as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q for the period ended September 30, 2022 (the "Form 10-Q"), filed concurrently herewith by the Company, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2022

By: /s/ Joseph E. Payne
Joseph E. Payne
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, the Chief Financial Officer of Arcturus Therapeutics Holdings Inc. (the "Company"), hereby certifies on the date hereof, pursuant to 18 U.S.C. 1350(a), as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q for the period ended September 30, 2022 (the "Form 10-Q"), filed concurrently herewith by the Company, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2022

By: /s/ Andy Sassine
Andy Sassine
Chief Financial Officer