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

Form 10-Q

X **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended: September 30, 2021 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: 001-36066

PARATEK PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0960223**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

75 Park Plaza
Boston, MA 02116
(617) 807-6600
(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

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	PRTK	The Nasdaq Global Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	X	Smaller reporting company	X
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 Act). Yes ☐ No X

As of October 29, 2021, there were 50,188,851 shares of the registrant's common stock, par value $0.001 per share, outstanding.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Paratek Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except for share and par value amounts)
(unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 110,999	$ 105,157
Marketable securities	-	20,005
Restricted cash	125	891
Accounts receivable, net	21,862	11,878
Inventories	8,824	14,555
Other receivables	270	3,855
Prepaid and other current assets	10,931	7,776
Total current assets	153,011	164,117
Long-term restricted cash	125	-
Fixed assets, net	872	964
Goodwill	829	829
Right-of-use assets	1,816	2,010
Long-term inventories	23,895	8,728
Other long-term assets	1,800	205
Total assets	$ 182,348	$ 176,853
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 4,991	$ 1,813
Accrued expenses	23,164	20,826
Other current liabilities	995	1,314
Total current liabilities	29,150	23,953
Long-term debt	253,269	250,474
Long-term lease liabilities	1,391	1,544
Other liabilities	3,531	3,142
Total liabilities	287,341	279,113
Commitments and contingencies (Note 17)		
Stockholders' deficit		
Preferred stock:		
Undesignated preferred stock: $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized; 50,020,217 shares issued and outstanding as of September 30, 2021; and 100,000,000 shares authorized; 46,516,567 shares issued and outstanding as of December 31, 2020	50	46
Additional paid-in capital	729,587	705,489
Accumulated other comprehensive income	-	4
Accumulated deficit	(834,630)	(807,799)
Total stockholders' deficit	(104,993)	(102,260)
Total liabilities and stockholders' deficit	$ 182,348	$ 176,853

See accompanying notes to unaudited condensed consolidated financial statements.

Paratek Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue, net	$ 19,432	$ 10,895	$ 85,441	$ 26,330
Government contract service revenue	1,467	785	4,553	1,560
Government contract grant revenue	3,011	1,866	6,712	2,303
Collaboration and royalty revenue	537	113	1,659	710
Net revenue	$ 24,447	$ 13,659	$ 98,365	$ 30,903
Expenses:				
Cost of product revenue	4,289	2,017	16,817	5,724
Research and development	7,920	6,687	19,977	17,636
Selling, general and administrative	25,955	20,902	75,420	65,514
Total operating expenses	38,164	29,606	112,214	88,874
Loss from operations	(13,717)	(15,947)	(13,849)	(57,971)
Other income and expenses:				
Interest income	25	280	61	1,347
Interest expense	(4,367)	(5,178)	(13,019)	(14,974)
Other gains (losses), net	(143)	(10)	(24)	67
Net loss	$ (18,202)	$ (20,855)	$ (26,831)	$ (71,531)
Other comprehensive income (loss)				
Unrealized gain (loss) on available-for-sale securities, net of tax	—	(154)	(4)	26
Comprehensive loss	$ (18,202)	$ (21,009)	$ (26,835)	$ (71,505)
Basic and diluted net loss per common share	$ (0.37)	$ (0.46)	$ (0.56)	$ (1.64)
Weighted average common stock outstanding				
Basic and diluted	49,213,986	45,483,346	47,676,365	43,591,724

See accompanying notes to unaudited condensed consolidated financial statements.

Paratek Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	For the Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (26,831)	$ (71,531)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion	313	437
Stock-based compensation expense	9,480	7,925
Noncash interest expense	996	5,364
Changes in operating assets and liabilities		
Accounts receivable, other receivables, prepaid, and other current assets	(9,368)	(8,707)
Inventories	(9,435)	(7,099)
Operating lease right-of-use asset	194	593
Accounts payable and accrued expenses	7,866	(3,754)
Operating lease liability	(153)	(730)
Other liabilities and other assets	(1,527)	(2,072)
Net cash used in operating activities	(28,465)	(79,574)
Investing activities		
Purchase of fixed assets	(373)	(331)
Purchase of marketable securities	—	(29,625)
Proceeds from maturities of marketable securities	20,000	95,500
Net cash provided by investing activities	19,627	65,544
Financing activities		
Payment of long-term royalty-backed loan agreement debt issuance costs	(397)	—
Proceeds from sale of common stock, net of costs	14,078	21,892
Principal payments on long-term debt	—	(10,000)
Proceeds from the employee stock purchase plan and stock options	358	324
Net cash provided by financing activities	14,039	12,216
Net (decrease) increase in cash, cash equivalents and restricted cash	5,201	(1,814)
Cash, cash equivalents and restricted cash at beginning of period	106,048	105,633
Cash, cash equivalents and restricted cash at end of period	$ 111,249	$ 103,819
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash paid for interest	$ 7,664	$ 13,771
Purchases of equipment included in accrued expenses	$ —	$ 45
SUPPLEMENTAL DISCLOSURES OF NONCASH FINANCING ACTIVITIES		
Fair value of warrants issued	$ —	$ 1,127
Paid in-kind interest included in accrued expenses	$ 1,801	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

Paratek Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at December 31, 2020	46,516,567	$ 46	$ 705,489	$ 4	$ (807,799)	$ (102,260)
Vesting of restricted stock unit awards	389,700	1	(1)	—	—	—
Exercise of stock options	961	—	3	—	—	3
Employee stock purchase plan expense	—	—	27	—	—	27
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(4)	—	(4)
Stock-based compensation expense	—	—	1,572	—	—	1,572
Net loss	—	—	—	—	(18,346)	(18,346)
Balances at March 31, 2021	46,907,228	$ 47	$ 707,090	$ —	$ (826,145)	$ (119,008)
Issuance of common stock, net of expenses	649,022	1	4,644	—	—	4,645
Vesting of restricted stock unit awards	376,301	—	—	—	—	—
Employee stock purchase plan expense	—	—	29	—	—	29
Issuance of stock under the employee stock purchase plan	63,920	—	352	—	—	352
Stock-based compensation expense	—	—	4,974	—	—	4,974
Net income	—	—	—	—	9,717	9,717
Balances at June 30, 2021	47,996,471	$ 48	$ 717,089	$ 0	$ (816,428)	$ (99,291)
Exercise of stock options	848	—	4	—	—	4
Issuance of common stock, net of expenses	1,657,802	2	9,615	—	—	9,617
Vesting of restricted stock unit awards	365,096	—	—	—	—	—
Employee stock purchase plan expense	—	—	37	—	—	37
Stock-based compensation expense	—	—	2,842	—	—	2,842
Net income	—	—	—	—	(18,202)	(18,202)
Balances at September 30, 2021	50,020,217	$ 50	$ 729,587	$ 0	$ (834,630)	$ (104,993)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at December 31, 2019	39,827,749	$ 40	$ 671,497	$ 74	$ (711,258)	$ (39,647)
Issuance of common stock, net of expenses	2,334,107	2	9,092	—	—	9,094
Vesting of restricted stock unit awards	212,170	—	—	—	—	—
Employee stock purchase plan expense	—	—	35	—	—	35
Unrealized gain on available-for-sale securities, net of tax	—	—	—	397	—	397
Stock-based compensation expense	—	—	2,500	—	—	2,500
Net loss	—	—	—	—	(27,617)	(27,617)
Balances at March 31, 2020	42,374,026	$ 42	$ 683,124	$ 471	$ (738,875)	$ (55,238)
Issuance of common stock, net of expenses	2,603,171	3	11,740	—	—	11,743
Vesting of restricted stock unit awards	200,500	—	—	—	—	—
Employee stock purchase plan expense	—	—	36	—	—	36
Issuance of stock under the employee stock purchase plan	130,055	—	324	—	—	324
Unrealized gain on available-for-sale securities, net of tax	—	—	—	(217)	—	(217)
Stock-based compensation expense	—	—	2,953	—	—	2,953
Net loss	—	—	—	—	(23,059)	(23,059)
Balances at June 30, 2020	45,307,752	$ 45	$ 698,177	$ 254	$ (761,934)	$ (63,458)
Issuance of common stock, net of expenses	238,722	1	1,054	—	—	1,055
Vesting of restricted stock unit awards	92,932	—	—	—	—	—
Employee stock purchase plan expense	—	—	37	—	—	37
Unrealized gain on available-for-sale securities, net of tax	—	—	—	(154)	—	(154)
Stock-based compensation expense	—	—	2,364	—	—	2,364
Issuance of warrants for common stock	—	—	1,127	—	—	1,127
Net loss	—	—	—	—	(20,855)	(20,855)
Balances at September 30, 2020	45,639,406	$ 46	$ 702,759	$ 100	$ (782,789)	$ (79,884)

1. Description of the business

Paratek Pharmaceuticals, Inc., or the Company or Paratek, is a Delaware corporation with its corporate office in Boston, Massachusetts and an office in King of Prussia, Pennsylvania.

The Company is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel life-saving therapies for life-threatening diseases or other public health threats for civilian, government and military use. The Company's United States, or U.S., Food and Drug Administration, or FDA, approved commercial product, NUZYRA® (omadacycline), is a once-daily oral and intravenous antibiotic for the treatment of adult patients with community-acquired bacterial pneumonia, or CABP, and acute skin and skin structure infections, or ABSSSI, caused by susceptible pathogens. SEYSARA® (sarecycline) is an FDA-approved product with respect to which the Company has exclusively licensed in the U.S. and the People's Republic of China, or the PRC, Hong Kong and Macau, or the greater China region, certain rights to Almirall, LLC, or Almirall. SEYSARA is currently being marketed by Almirall in the U.S. as a once-daily oral therapy for the treatment of moderate to severe acne vulgaris. With respect to the Company's technology as it relates to sarecycline, the Company retains development and commercialization rights in all countries other than the U.S. and the greater China region, and in February 2020, the Company exclusively licensed from Almirall certain technology owned or in-licensed by Almirall or its affiliates that is necessary or useful to develop or commercialize sarecycline outside of the U.S. Almirall plans to develop sarecycline for acne in China.

The Company has incurred significant losses since inception in 1996. The Company has generated an accumulated deficit of $834.6 million through September 30, 2021 and may require substantial additional funding in connection with the Company's continuing operations to support clinical development and commercialization activities associated with NUZYRA. Based upon the Company's current operating plan, it anticipates that its cash and cash equivalents of $111.0 million as of September 30, 2021 will enable the Company to fund operating expenses and capital expenditure requirements through at least the next twelve months from the issuance of the financial statements included in this Quarterly Report on Form 10-Q. The Company expects to finance future cash needs primarily through a combination of product sales, royalties, public or private equity offerings, debt or other structured financings, strategic collaborations, grant funding and government funding. The Company is subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain additional financing to fund the future development of the Company's product candidates, the need to obtain compliant product from third-party manufacturers, the need to obtain marketing approval for the Company's product candidates, the need to successfully commercialize and gain market acceptance of product candidates, the risks of manufacturing product with an external supply chain, dependence on key personnel, and compliance with government regulations as well as the risks discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the U.S. Securities and Exchange Commission, or the SEC, on March 29, 2021, or the 2020 Form 10-K, in the Company's other filings with the SEC and in the "Risk Factors" section of this Quarterly Report on Form 10-Q.

2. Summary of Significant Accounting Policies and Basis of Presentation

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, of the Financial Accounting Standards Board, or FASB, and pursuant to the rules and regulations of the SEC.

The accompanying condensed consolidated financial statements are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2020, and, in the opinion of management, reflect all normal recurring adjustments necessary for the fair presentation of the Company's financial position as of September 30, 2021 and December 31, 2020, results of operations for the three and nine month periods ended September 30, 2021 and September 30, 2020, cash flows for the nine month periods ended September 30, 2021 and September 30, 2020 and changes in stockholders' deficit for the three and nine month periods ended September 30, 2021 and September 30, 2020. Long-term inventories of $8.7 million, which was included in other long-term assets on the December 31, 2020 balance sheet, has been reclassified to conform to the fiscal year 2021 presentation.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2021. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2020, and notes thereto, which are included in the Company's 2020 Form 10-K.

Summary of Significant Accounting Policies

As of September 30, 2021, the Company's significant accounting policies and estimates, which are detailed in the Company's 2020 Form 10-K, have not changed.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the results of operations of Paratek Pharmaceuticals, Inc. and its wholly-owned subsidiaries, Paratek Pharma, LLC, Paratek Securities Corporation, Transcept Pharma, Inc., Paratek UK Limited, Paratek Ireland Limited, Paratek Royalty Corporation, Paratek Royalty Corporation II, PRTK SPV1 LLC and PRTK SPV2 LLC. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the accompanying unaudited condensed consolidated financial statements, in conformity with U.S. GAAP, requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses in the Company's financial statements. On an ongoing basis, the Company evaluates its estimates and judgments, including those related to, among other items, accounts receivable and related reserves, inventory and related reserves, goodwill, net product revenue, government contract service revenue, government contract grant revenue, collaboration and royalty revenue, leases, stock-based compensation arrangements, amortization of the debt discount and issuance costs under the R-Bridge Loan Agreement (as defined below), manufacturing and clinical accruals, useful lives for depreciation and valuation allowances on deferred tax assets. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known by the Company's management.

Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash, restricted cash, and accounts receivable. The Company places its cash in an accredited financial institution and this balance is above federally insured amounts. The Company has no off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Accounts receivable as of September 30, 2021 includes $18.6 million due from customers for sales of NUZYRA, net of prompt payment discounts, chargebacks, rebates and certain fees. Accounts receivable as of September 30, 2021 also includes $0.6 million of government contract service revenue earned under the BARDA contract, $2.1 million of government contract grant revenue earned under the BARDA contract, and estimated revenue earned of $0.5 million of royalties on SEYSARA sales under the Almirall Collaboration Agreement (as defined below) and XERAVA ™ (eravacycline) sales under the Tetraphase License Agreement (as defined below). Refer to Note 7, *Government Contract Revenue* for further information on the BARDA contract and to Note 8, *License and Collaboration Agreements* for further information on the Almirall Collaboration Agreement and the Tetraphase License Agreement.

3. Marketable Securities

The Company did not hold any available-for-sale securities as of September 30, 2021.

The following is a summary of available-for-sale securities as of December 31, 2020 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2020				
U.S. treasury securities	$ 20,001	$ 4	$ —	$ 20,005
Total	$ 20,001	$ 4	$ —	$ 20,005

No available-for-sale securities held as of December 31, 2020 had remaining maturities greater than twelve months.

4. Cash and Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated statement of cash flows that sum to the total of the same such amounts shown in the condensed consolidated statement of cash flows (in thousands):

	September 30, 2021	September 30, 2020
Cash and cash equivalents	$ 110,999	$ 102,356
Short-term restricted cash	125	1,463
Long-term restricted cash	125	-
Total cash, cash equivalents and restricted cash shown on the condensed consolidated statement of cash flows	$ 111,249	$ 103,819

Short-term restricted cash

On May 1, 2019, the Company deposited $4.0 million into an interest reserve account in conjunction with the funding of a royalty-backed loan agreement, or the Royalty-Backed Loan Agreement, executed with Healthcare Royalty Partners III, L.P., or HCRP. Payments of interest under the Royalty-Backed Loan Agreement are made quarterly using royalty payments received since the immediately preceding payment date under the Almirall Collaboration Agreement. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the Company will cover the balance of the interest payment due from the interest reserve account. Refer to Note 13, *Long-Term Debt,* for further details. There was no restricted cash related to the Royalty-Backed Loan Agreement as of September 30, 2021. As of December 31, 2020, $0.6 million of restricted cash represented the estimated amount that is expected to be paid to HCRP out of the interest reserve account within the next twelve months.

The Company leases its Boston, Massachusetts office space under a non-cancelable operating lease. In accordance with the lease, the Company has a cash-collateralized irrevocable standby letter of credit in the amount of $0.3 million as of both September 30, 2021 and December 31, 2020, naming the landlord as beneficiary. The Company executed an amendment to the existing lease agreement on its Boston office space in April 2021. In accordance with the amendment, the cash-collateralized irrevocable standby letter of credit was reduced to an insignificant amount during the three months ended September 30, 2021 and reclassified as long-term restricted cash as of September 30, 2021. The portion of the letter of credit expected to be received in the next twelve months is classified as short-term restricted cash as of September 30, 2021. Refer to Note 14, *Leases*, for further details.

Long-term restricted cash

As of September 30, 2021, long-term restricted cash included the insignificant cash-collateralized irrevocable standby letter of credit described above.

5. Inventories

The following table presents inventories, net (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 903	$ 720
Work in process	23,239	12,925
Finished goods	8,577	9,638
Total inventories	$ 32,719	$ 23,283

When recorded, inventory reserves reduce the carrying value of inventories to their net realizable value. The Company reviews inventories on hand at least quarterly and records provisions for estimated excess, slow-moving and obsolete inventory, as well as inventory with a carrying value in excess of net realizable value. No inventory reserves existed as of September 30, 2021 and December 31, 2020.

6. Net Income (Loss) Per Share

Basic net income (loss) per share is based upon the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net income (loss) per share is based upon the weighted-average number

of common shares outstanding during the period plus the effect of additional weighted-average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. For purposes of this calculation, shares of common stock issuable upon conversion of convertible debt, stock options, restricted stock units, or RSUs, warrants to purchase common stock, and shares issuable under the Company's employee stock purchase plan are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Common equivalent shares result from the assumed exercise of outstanding stock options and the exercise of outstanding warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options. The two-class method is used for outstanding warrants as it is considered to be a participating security, and it is more dilutive than the treasury stock method.

The Company was in a net loss position as of September 30, 2021. The following outstanding shares subject to stock options and RSUs, warrants to purchase shares of common stock, common stock issuable upon conversion of convertible debt and shares issuable under the Company's employee stock purchase plan were antidilutive due to a net loss in the periods presented and, therefore, were excluded from the dilutive securities computation for the three and nine months ended September 30, 2021 and 2020 as indicated below:

	September 30,	
	2021 (1)	2020 (1)
Convertible notes	10,377,361	10,377,361
Warrants	469,388	479,002
Stock options	2,059,453	2,032,295
Unvested restricted stock units	5,677,110	4,195,592
Employee stock purchase plan	542,896	668,132
Totals	19,126,208	17,752,382

(1) The number of shares is based on the maximum number of shares issuable on exercise or conversion of the related securities as of September 30, 2021 and 2020. Such amounts have not been adjusted for the treasury-stock method or weighted-average outstanding calculations as required if the securities were dilutive.

7. Government Contract Revenue

Biomedical Advanced Research and Development Authority

On December 18, 2019, the Company entered into a five-year contract with the Biomedical Advanced Research and Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services', or HHS, Office of the Assistant Secretary for Preparedness and Response, herein referred to as the BARDA contract, with an option to extend up to ten years, to support the development of NUZYRA for the treatment of pulmonary anthrax, FDA post-marketing requirements, or PMRs, associated with the initial NUZYRA approval, and the ability for BARDA to procure up to 10,000 treatment courses of NUZYRA.. On September 27, 2021, the Company and BARDA modified the original BARDA contract, herein referred to as the amended BARDA contract, to provide additional funding to expand the development of NUZYRA under an FDA Animal Efficacy Rule development program to support a supplemental New Drug Application, or sNDA, to the FDA to include post-exposure prophylaxis, or PEP, in addition to the treatment of pulmonary anthrax, herein referred to as an amended option.

The amended BARDA contract could result in payments to the Company of up to approximately $303.6 million and consists of a five-year base period-of-performance and a total contract period-of-performance (base period plus option exercises) of up to ten years. Under the base period-of-performance, the Company will conduct activities necessary to (i) allow the product to be used under an Emergency Use Authorization, (ii) obtain licensure of NUZYRA through an sNDA , submission for treatment and PEP of pulmonary anthrax, and (iii) provide up to 2,500 treatment courses of the drug product to be stored as vendor managed inventory.

Under the terms of the BARDA contract, approximately $59.4 million for the development of NUZYRA for the treatment of pulmonary anthrax and the purchase of an initial 2,500 treatment courses of NUZYRA was awarded to the Company by BARDA in December 2019. As part of this initial $59.4 million award, the first $37.9 million procurement of NUZYRA was delivered to and accepted by BARDA in June 2021, and the amount earned from this procurement was recognized in net U.S. sales of NUZYRA during the second quarter of 2021. The Company has been periodically drawing down the remaining $21.5 million of the initial award based on costs incurred during the development program.

Two additional contractual services were initiated by BARDA in April 2020 that awarded the Company approximately $76.8 million for reimbursement of existing FDA PMRs and approximately $20.4 million for reimbursement of manufacturing-related requirements, which the Company has been drawing down based on costs incurred. This additional staged funding is expected to support all FDA PMRs associated with the approval of NUZYRA, including CABP and pediatric studies, as well as a five-year post-marketing bacterial surveillance study, and support the U.S. onshoring and security requirements of the Company's manufacturing activities for NUZYRA.

BARDA initiated the amended option in September 2021 that awarded the Company additional funding of approximately $18.9 million to expand the development of NUZYRA under an FDA Animal Efficacy Rule development program to support an sNDA that will include post-exposure prophylaxis, or PEP, in addition to the treatment of pulmonary anthrax, for total funding of the amended option of approximately $31.6 million.

The remaining awards under the BARDA contract include a maximum of approximately $115.3 million to provide for three additional purchases of NUZYRA anthrax treatment courses, each of which may be exercised at BARDA's discretion upon achievement of development milestones related to the anthrax treatment development program.

The BARDA contract contains a number of terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

The Company evaluated the BARDA contract under ASC, Topic 606, *Revenue from Contracts with Customers*, or ASC 606, and concluded that a portion of the arrangement represents a transaction with a customer. The Company identified five material promises under the BARDA contract: (i) research and development services performed for the treatment of pulmonary anthrax, (ii) the procurement of 2,500 treatment courses of NUZYRA, (iii) an option for services performed for the supplemental late-stage development of NUZYRA for treatment and prophylaxis of pulmonary anthrax, (iv) an option for services related to U.S. manufacturing onshoring and security requirements, which includes shelf-life stability extension work and regulatory activities that will benefit the manufacturing processes that support NUZYRA for the treatment of pulmonary anthrax, and (v) options to procure up to three tranches of up to 2,500 anthrax treatment courses of NUZYRA each.

In December 2019, the Company determined material promises (i) and (ii) above were performance obligations since they were distinct within the context of the contract as the services are separately identifiable from other promises within the arrangement. The Company also determined that for (i) and (ii) the transaction price included within the BARDA contract was equivalent to the standalone selling price of the services and the cost of the procurement.

The Company evaluated the material promises that contained option rights ((iii), (iv), and (v) above). The Company determined that (iii) and (iv) were not offered at a discount that is incremental to the range of discounts typically given for these goods and services, and therefore do not represent material rights. As such, options for additional services in (iii) and (iv) were not considered performance obligations at the outset of the arrangement. The Company also evaluated the future procurement option rights (v) and determined that those option rights represent a material right. As such, the optional additional NUZYRA procurements in (v) were considered performance obligations at the outset of the arrangement. The Company concluded that three performance obligations existed at the outset of the BARDA contract.

As the BARDA contract is partially within the scope of ASC 606 and partially within the scope of other guidance, the Company applied the guidance of ASC 606 to initially measure the parts of the contract to which ASC 606 is applicable. The total transaction price of the parts of the BARDA contract that existed at the outset of the contract that fall under ASC 606 was determined to be $63.6 million, inclusive of $4.2 million in variable consideration and was allocated to each of the three performance obligations based on the performance obligation's estimated relative stand-alone selling prices. As of September 30, 2021, the Company reevaluated the variable consideration of $4.2 million that is included in the transaction price and determined that the variable consideration should not be constrained as it is not probable that a significant reversal in the amount of the cumulative revenue recognized will occur in a future period. The transaction price was allocated as follows: $21.5 million to research and development services performed for the treatment of pulmonary anthrax in (i), which will be classified as government contract service revenue when recognized, $37.9 million to the procurement of 2,500 treatment courses of NUZYRA in (ii), which will be classified as product revenue when recognized, and a total of $4.2 million to the options to procure up to three 2,500 treatment courses of NUZYRA in (v), which will be included within product revenue when recognized upon exercise and transfer of control of related treatment courses. The Company estimated the stand-alone selling price of the research and development services performed for the treatment of pulmonary anthrax based on the Company's projected cost of providing the services plus an applicable profit margin commensurate with observable market data for similar services. The Company estimated the stand-alone selling price of the procurement of 2,500 treatment courses of NUZYRA based on historical pricing of the Company's commercial products to similar customers. The Company estimated the stand-alone selling price of the future procurement options based on the discount that the customer would obtain when exercising the option,

adjusted for any discount that the customer could receive without entering into the contract, and the likelihood that the option will be exercised.

The Company's performance obligations are either satisfied over time as work progresses or at a point in time.

The Company concluded that research and development services performed for the treatment of pulmonary anthrax in (i) would be recognized as government contract service revenue over time as the performance obligation is satisfied. Costs incurred represent work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Types of contract costs include labor, material, and third-party services.

The product procurement performance obligations ((ii) and, if any optional additional procurements are exercised from (v) above), generate revenue at a point in time, upon transfer of control of the product. As such, the related revenue for these performance obligations is recognized at a point in time as product revenue within the Company's consolidated statement of operations. As of September 30, 2021, the product procurement performance obligation (ii) was completed and $37.9 million of product revenue was earned and recognized due to the delivery and acceptance of the first procurement under the BARDA contract.

In April 2020, BARDA exercised its option to obtain manufacturing-related services under material promise (iv) and the Company is treating these services as a separate $20.4 million contract for accounting purposes since manufacturing-related services were determined at the contract outset to be optional services that did not represent a material right. The Company's manufacturing-related services are satisfied over time as work progresses.

In September 2021, BARDA exercised the amended option under the amended BARDA contract, to fund an FDA Animal Rule development program to support an sNDA for the treatment of and the PEP against pulmonary anthrax. The Company is treating these services as a separate $31.6 million contract for accounting purposes since the completion of a late-stage development program was determined at the contract outset to be optional services that did not represent a material right. The additional services added as part of the amended option were distinct and the increased transaction price is reflective of the entity's standalone selling prices of the additional promised services. The Company's late-stage development program obligations are satisfied over time as work progresses. Research and development services performed under the amended option will be recognized as government contract service revenue over time as the performance obligation is satisfied.

The Company recognized $1.5 million and $4.6 million of government contract service revenue under the BARDA contract during the three and nine months ended September 30, 2021, respectively.

As of September 30, 2021, the aggregate amount of transaction price allocated to remaining performance obligations, excluding unexercised contract options, was $39.8 million. The Company expects to recognize this amount as revenue over the next three to six years.

The Company concluded that BARDA's reimbursement for existing FDA PMRs associated with the initial NUZYRA approval was not within the scope of ASC 606 as BARDA is not receiving services as the Company's customer. The Company estimated the consideration to be allocated to government contract grant revenue based on the consideration under the BARDA contract in excess of the estimated standalone selling prices for components of the BARDA contract accounted for under ASC 606. The Company recognizes the allocated consideration for BARDA's reimbursement of existing FDA PMRs associated with the initial NUZYRA approval of $72.6 million as government contract grant revenue as the related reimbursable expenses are incurred.

The Company recognized $3.0 million and $6.7 million of government contract grant revenue under the BARDA contract during the three and nine months ended September 30, 2021, respectively.

Contract Balances

Contract assets (i.e., unbilled accounts receivable) and/or contract liabilities (i.e., customer advances and deposits) may exist at the end of each reporting period under the BARDA contract. When amounts are received prior to performance obligations being satisfied, the amounts allocated to those performance obligations are reflected as contract liabilities on the consolidated balance sheets, as deferred revenue, until the performance obligations are satisfied.

As of September 30, 2021, $1.4 million of unbilled accounts receivable was recorded and is a component of accounts receivable, net on the Company's condensed consolidated balance sheet.

As of September 30, 2021, an insignificant amount of deferred revenue was recorded and is a component of other current liabilities on the Company's condensed consolidated balance sheet.

As of September 30, 2021, $0.6 million of deferred revenue was recorded and is a component of other liabilities on the Company's condensed consolidated balance sheet.

8. License and Collaboration Agreements

Tetraphase Pharmaceuticals, Inc.

On March 18, 2019, Paratek and Tetraphase Pharmaceuticals, Inc., or Tetraphase, which is now a subsidiary of La Jolla Pharmaceutical Company, entered into a License Agreement, or the Tetraphase License Agreement. Under the terms of the Tetraphase License Agreement, Paratek granted to Tetraphase a non-exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, under certain Paratek patents, to develop, make, have, use, import, offer for sale and sell the licensed product, or XERAVA, which is a drug for the treatment of complicated, intra-abdominal infections caused by bacteria, which was approved by the FDA in August 2018.

The terms of the Tetraphase License Agreement provide for Tetraphase to pay Paratek royalties at a low single digit percent on net product revenues of the licensed product sold in the U.S. Tetraphase's obligation to pay royalties with respect to the licensed product shall be retroactive to the date of the first commercial sale of the licensed product in the U.S., which occurred in February 2019. Tetraphase is currently selling XERAVA in the U.S.

In accordance with the Company's revenue recognition policy, the Company recognized an insignificant amount of royalty revenue during the three and nine months ended September 30, 2021 under the Tetraphase License Agreement.

Zai Lab (Shanghai) Co., Ltd.

On April 21, 2017, Paratek Bermuda Ltd., a former wholly-owned subsidiary of Paratek Pharmaceuticals, Inc., and Zai Lab (Shanghai) Co., Ltd., or Zai, entered into a License and Collaboration Agreement, or the Zai Collaboration Agreement. On December 18, 2019, Paratek Bermuda Ltd. assigned its rights under the Zai Collaboration Agreement to Paratek Pharmaceuticals, Inc. Under the terms of the Zai Collaboration Agreement, Paratek granted Zai an exclusive license to develop, manufacture and commercialize omadacycline, or the licensed product, in the PRC, Hong Kong, Macau and Taiwan, or the Zai territory, for all human therapeutic and preventative uses other than biodefense. Zai will be responsible for the development, manufacturing and commercialization of the licensed product in the Zai territory, at its sole cost with certain assistance from Paratek.

Under the terms of the Zai Collaboration Agreement, Paratek is eligible to receive up to $6.0 million in potential future regulatory milestone payments and $40.5 million in potential future commercial milestone payments, the next being $6.0 million upon regulatory approval for a licensed product in the PRC. The terms of the Zai Collaboration Agreement also provide for Zai to pay Paratek tiered royalties at a low double digit to mid-teen percent on net sales of the licensed product in the Zai territory. In accordance with the Company's revenue recognition policy, as regulatory approval in the PRC is not within the control of the Company, the achievement of the milestone was not deemed probable and the risk of significant reversal of revenue was not resolved as of September 30, 2021. As such, the next milestone payment was not recognized as revenue during the nine months ended September 30, 2021.

Almirall, LLC

In July 2007, the Company and Warner Chilcott Company, Inc. (which became a part of Allergan plc, or Allergan), entered into a collaborative research and license agreement under which the Company granted Allergan an exclusive license to research, develop, manufacture and commercialize tetracycline products for use in the U.S. for the treatment of acne and rosacea. In September 2018, Allergan assigned to Almirall its rights under the collaboration agreement, or the Almirall Collaboration Agreement. Since Allergan did not exercise its development option with respect to the treatment of rosacea prior to initiation of a Phase 3 trial for the product, the license grant to Allergan, which was assigned to Almirall, converted to a non-exclusive license for the treatment of rosacea as of December 2014.

Under the terms of the Almirall Collaboration Agreement, Almirall is responsible for and is obligated to use commercially reasonable efforts to develop and commercialize tetracycline compounds that are specified in the agreement for the treatment of acne. The Company has agreed during the term of the Almirall Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compounds in the U.S. for the treatment of acne, and Almirall has agreed during the term of the Almirall Collaboration Agreement not to directly or indirectly develop or commercialize any tetracycline compound included as part of the agreement for any use other than as provided in the Almirall Collaboration Agreement.

In February 2020, the Company finalized a license agreement with Almirall granting the Company exclusive rights to develop, manufacture and commercialize sarecycline outside of the U.S., including rights of reference to Almirall's clinical data thus formalizing the Company's rights to develop, manufacture and commercialize sarecycline in the rest of the world. In connection with that license, the Company then exclusively licensed Almirall pursuant to the Almirall China License Agreement, the rights to develop, manufacture and commercialize sarecycline in the greater China region. Almirall currently holds a nonexclusive license to develop and commercialize sarecycline for the treatment of rosacea in the U.S., and in the U.S., Paratek cannot grant rights on back-up compounds, lead candidate(s), or products licensed to Almirall for rosacea.

The Almirall Collaboration Agreement contains two performance obligations: (i) an exclusive license to research, develop and commercialize tetracycline products for use in the U.S. for the treatment of acne and rosacea and (ii) research and development services. The performance obligation to deliver the license was satisfied upon execution of the Almirall Collaboration Agreement in July 2007. All research and development services were completed by December 2010. As of December 2010, the Company had no remaining performance obligations under the Almirall Collaboration Agreement.

Almirall is also obligated to pay the Company tiered royalties, ranging from the mid-single digits to the low double digits, based on net sales of tetracycline compounds developed under the Almirall Collaboration Agreement, with a standard royalty reduction post patent expiration for such product for the remainder of the royalty term.

Royalty payments are recognized when the sales occur. The Company recognized $0.5 million and $1.5 million of royalty revenue for sales of SEYSARA in the U.S. by Almirall for the three and nine months ended September 30, 2021, respectively, under the Almirall Collaboration Agreement. During the third quarter of 2021, royalty revenue recognized for sales of SEYSARA in the U.S. was estimated using third-party data and an approximation of discounts and allowances to calculate net product sales, to which the Company then applied the applicable royalty percentage specified in the Almirall Collaboration Agreement. Differences between actual and estimated royalty revenues will be adjusted for in the period in which they become known, which is expected to be the following quarter.

In February 2020, the Company entered into (i) an ex-U.S. license agreement with Almirall, or the Ex-U.S. License, under which Almirall granted the Company an exclusive license in and to certain technology owned or in-licensed by Almirall or its affiliates in order to research, develop, manufacture and commercialize sarecycline for the treatment of acne in all countries other than the U.S. and (ii) a license agreement with Almirall that is specific to China, or the China License, under which the Company granted to Almirall an exclusive license in and to certain technology owned or in-licensed by the Company or its affiliates in order to research, develop and commercialize sarecycline for the treatment of acne in the greater China region.

Under the terms of the China License, Almirall is responsible for and is obligated to use commercially reasonable efforts to develop and commercialize sarecycline for the treatment of acne, including requirements to (i) file an Investigational New Drug Application (or analogous foreign submission) for sarecycline for the treatment of acne in the greater China region in calendar year 2020, (ii) receive regulatory approval for sarecycline for the treatment of acne in the greater China region within seven years following such submission and (iii) commercialize sarecycline for the treatment of acne in the greater China region within eighteen months after obtaining regulatory approval. If Almirall does not satisfy the diligence requirements set forth in subclauses (ii) or (iii) above, the Company may terminate the China License.

In connection with the Ex-U.S. License, the Company pays Almirall, on a country-by-country and product-by-product basis, (i) for eight years following the first commercial sale of a sarecycline product in a country, a royalty in the middle-single digits on its or its affiliates' nets sales of sarecycline products outside of the U.S., subject to certain standard reductions, and (ii) for fifteen years following the first commercial sale of a sarecycline product in a country, a percentage of the consideration (e.g., milestones, royalties) we receive from sublicensees in connection with developing and commercializing sarecycline outside of the U.S., which ranges from one-fifth to one-half of such consideration, subject to certain standard reductions. In connection with the China License, for fifteen years following the first commercial sale of a sarecycline product in China, Almirall pays the Company a royalty in the high-single digits on their, their affiliates' or their sublicensees' net sales of sarecycline products in the greater China region, subject to certain standard reductions.

Tufts University

In February 1997, the Company and Tufts University, or Tufts, entered into a license agreement under which the Company acquired an exclusive license to certain patent applications and other intellectual property of Tufts related to the drug resistance field to develop and commercialize products for the treatment or prevention of bacterial or microbial diseases or medical conditions in humans or animals or for agriculture. The Company subsequently entered into eleven amendments to that agreement, collectively the Tufts License Agreement, to include patent applications filed after the effective date of the original license agreement, to exclusively license additional technology from Tufts, to expand the field of the agreement to include disinfectant applications, and to change the royalty rate and percentage of sublicense income paid by the Company to Tufts under sublicense agreements with specified sublicensees.

Past Collaborations

Novartis International Pharmaceutical Ltd.

In September 2009, the Company and Novartis International Pharmaceutical Ltd., or Novartis, entered into a Collaborative Development, Manufacture and Commercialization License Agreement, or the Novartis Agreement, which provided Novartis with a global, exclusive patent and technology license for the development, manufacturing and marketing of omadacycline. The Novartis Agreement was terminated by Novartis without cause in June 2011 and the termination was effective 60 days later. The Company and Novartis subsequently entered in a letter agreement in January 2012, or the Novartis Letter Agreement, as amended, pursuant to which we reconciled shared development costs and expenses and granted Novartis a right of first negotiation with respect to commercialization rights of omadacycline following approval of omadacycline from the FDA, European Medicines Agency, or any regulatory agency, but only to the extent the Company had not previously granted such commercialization rights related to omadacycline to another third party as of any such approval.

For additional information related to these agreements, as well as the Company's other significant collaborative agreements, please read Note 6, *License and Collaboration Agreements,* to the consolidated financial statements included within the Company's 2020 Form 10-K.

9. Capital Stock

On June 9, 2021, the Company's shareholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock of the Company to 200,000,000 shares from 100,000,000 shares. Subsequent to such approval, on June 10, 2021, the Company filed the Certificate of Amendment to its Amended and Restated Certificate of Incorporation with the Delaware Secretary of State, giving effect to the authorized share increase.

On May 17, 2021, the Company entered into an At-the-Market Sales Agreement, or the Sales Agreement, with BTIG, LLC, or BTIG, under which it may offer and sell its common stock having aggregate sales proceeds of up to $50.0 million from time to time through BTIG as its sales agent. Sales of the Company's common stock through BTIG, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including without limitation sales made directly on the Nasdaq Global Market or any other existing trading market for its common stock. BTIG will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay BTIG a commission of 3% of the gross sales proceeds of any common stock sold through BTIG under the Sales Agreement. The Company has also provided BTIG with customary indemnification rights.

The Company is not obligated to make any sales of common stock under the Sales Agreement. The offering of shares of the Company's common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement, or (ii) termination of the Sales Agreement in accordance with its terms.

The Company sold 2,300,425 shares of common stock pursuant to the Sales Agreement for $14.3 million in proceeds, after deducting an insignificant amount of commissions, during the nine months ended September 30, 2021. As of October 29, 2021, $34.4 million remains available for sale under the Sales Agreement.

On May 11, 2020, the Company filed a registration statement on Form S-3 with the SEC, as amended on June 19, 2020, and declared effective on July 9, 2020, to sell certain of its securities in an aggregate amount of up to $250.0 million. As of October 29, 2021, $234.4 million remains available on this shelf registration statement, with $34.4 million reserved for potential sales under the Sales Agreement.

10. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued compensation	$ 6,978	$ 7,783
Accrued sales allowances	5,725	3,429
Accrued interest	4,317	1,768
Accrued commercial	2,412	2,254
Accrued contract research	1,691	591
Accrued other	340	217
Accrued professional fees	518	1,209
Accrued manufacturing	363	972
Accrued legal costs	470	580
Accrued inventory	350	2,023
Total	$ 23,164	$ 20,826

11. Fair Value Measurements

Financial instruments, including cash, cash equivalents, restricted cash, money market funds, U.S. treasury securities, accounts receivable, accounts payable, and accrued expenses are carried on the condensed consolidated financial statements at amounts that approximate fair value. The fair value of the Company's long-term debt is determined using current applicable rates for similar instruments as of the balance sheet date. The fair value of the Company's debt (including the Notes as defined in Note 13, *Long-Term Debt)*, is $229.0 million as of September 30, 2021 and $223.5 million as of December 31, 2020. The fair value of the Company's debt was determined using Level 3 inputs. Fair values are based on assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

The following table presents information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2020 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value. The Company did not hold any U.S. treasury securities as of September 30, 2021. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities or other inputs that are observable market data. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability (in thousands):

Description	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
December 31, 2020				
Assets:				
U.S. treasury securities	$ 20,005	$ —	$ —	$ 20,005
Total Assets	$ 20,005	$ —	$ —	$ 20,005

12. Stock-Based and Incentive Compensation

Stock-based Compensation

The following table presents stock-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive income (loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expense	$ 519	$ 477	$ 1,637	$ 1,663
Selling, general and administrative expense	2,359	1,924	7,844	6,262
Total stock-based compensation expense	$ 2,878	$ 2,401	$ 9,481	$ 7,925

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period. The Company estimates the fair value of its stock options using the Black-Scholes option-pricing model. The weighted-average assumptions used to determine the fair value of the stock option grants is as follows:

	Nine Months Ended September 30,	
	2021	2020
Volatility	63.2%	63.0%
Risk-free interest rate	0.7%	0.9%
Expected dividend yield	0.0%	0.0%
Expected life of options (in years)	5.9	5.7

Stock Plan Activity

The Company's Board of Directors adopted the Paratek Pharmaceuticals, Inc. 2015 Equity Incentive Plan, or the 2015 Plan, which was approved by Company stockholders at the annual meeting of shareholders held on June 9, 2015. As of September 30, 2021, there are 265,884 shares available for future issuance under the 2015 Plan.

The Company recognizes the stock-based compensation expense of awards subject to performance-based vesting conditions over the requisite service period, to the extent achievement of the performance condition is deemed probable relative to targeted performance using the accelerated attribution method. A change in the requisite service period that does not change the estimate of the total stock-based compensation expense (i.e., it does not affect the grant-date fair value or quantity of awards to be recognized) is recognized prospectively over the remaining requisite service period.

During the nine months ended September 30, 2021, the Company's Board of Directors granted 82,617 stock options and 3,674,675 RSUs to directors, executives, and employees of the Company under the 2015 Plan. The stock option awards are subject to time-based vesting over a period of one to four years. The RSU awards granted to executives in March 2021 are subject to time-based vesting, with 1/3 of the shares vesting on December 10, 2021, and an additional 1/3 of the shares vesting on the succeeding two anniversaries of such date. The RSU awards granted to non-executive employees of the Company during March 2021 are subject to time-based vesting, with 1/3 of the shares vesting on February 18, 2022, and an additional 1/3 of the shares vesting on the succeeding two anniversaries of such date.

The March 2021 grants also included performance-based RSU, or PRSU, awards to certain executives and employees of the Company, which will vest as follows: (a) 25/55 on certain net product revenue achievements, (b) 10/55 on certain business achievements, (c) 10/55 on certain manufacturing achievements and (d) 10/55 on achievement of certain clinical milestones related to NUZYRA. Since the Company believes it is probable that milestone (d) above will be achieved, the Company recognized $0.4 million of stock-based compensation expense for the performance condition during the nine months ended September 30, 2021 using the accelerated attribution method.

During the year ended December 31, 2020, the Company's Board of Directors granted PRSU awards to certain executives and employees of the Company in February 2020 under the 2015 Plan that will vest as follows: (a) 25/55 on certain net product revenue achievements, (b) 15/55 on achievement of certain clinical milestones related to NUZYRA and (c) 15/55 on achievement of certain regulatory milestones related to NUZYRA. Since the Company believes it is probable that milestones (a) and (b) will be achieved, the Company recognized a cumulative catch-up of $1.2 million and $0.3 million of stock-based compensation expense, respectively, during the nine months ended September 30, 2021 using the accelerated attribution method. Milestone (c) was achieved and vested in May 2021, which resulted in a cumulative catch-up of $1.2 million of stock-based compensation expense during the nine months ended September 30, 2021.

During the year ended December 31, 2019, the Company's Board of Directors granted PRSU awards to certain executives and employees of the Company in February 2019 and July 2019 under the 2015 Plan that will vest as follows: (a) 25/60 and (b) 25/60, each, on certain net product revenue achievements and (c) the remaining 10/60 on certain other business achievements. Milestone (a) was achieved in September 2020 and vested during November 2020. Milestone (b) was achieved in June 2021 and will vest in August 2021. The Company believes it is probable that milestone (c) will be achieved. The Company recognized an insignificant amount of stock-based compensation expense for milestones (b) and (c) during the nine months ended September 30, 2021 using the accelerated attribution method.

The Company's Board of Directors adopted the Paratek Pharmaceuticals, Inc. 2015 Inducement Plan, or the 2015 Inducement Plan, in accordance with Nasdaq Rule 5635(c)(4), reserving 360,000 shares of common stock solely for the grant of inducement stock options to employees entering into employment or returning to employment after a bona fide period of non-employment with the Company. The Company has not made any grants under the 2015 Inducement Plan since December 31, 2015. Although the Company does not currently anticipate the issuance of additional grants under the 2015 Inducement Plan, as of September 30, 2021, 341,500 shares remain available for grant under that plan, as well as any shares underlying outstanding stock options that may become available for grant pursuant to the plan's terms. It is therefore possible that the Company may, based on the business and recruiting needs of the Company, issue additional stock options under the 2015 Inducement Plan.

In June 2017, the Company's Board of Directors adopted the Paratek Pharmaceuticals, Inc. 2017 Inducement Plan, or the 2017 Inducement Plan, in accordance with Nasdaq Rule 5635(c)(4), reserving 550,000 shares of common stock solely for the grant of inducement stock options and RSU awards to employees entering into employment or returning to employment after a bona fide period of non-employment with the Company. In October 2018, the Company's Board of Directors approved the reserve of an additional 500,000 shares for the 2017 Inducement Plan, for a total of 1,050,000 shares reserved for issuance under it. During the nine months ended September 30, 2021, the Company's Board of Directors granted 161,800 stock options and 73,500 RSUs to employees of the Company under the 2017 Inducement Plan. The stock option awards are subject to time-based vesting over a period of one to four years. The RSU awards are generally subject to time-based vesting, with 100% of the shares of common stock subject to the RSU award vesting three years from the grant date. As of September 30, 2021, 303,467 shares remain available for grant under the 2017 Inducement Plan, as well as any shares underlying awards that may become available for grant pursuant to the plan's terms.

Stock Options

A summary of stock option activity for the nine months ended September 30, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	1,986,442	$ 11.92	5.63	$ 1,748
Granted	244,417			
Exercised	(1,809)			
Cancelled or forfeited	(165,092)			
Expired	(4,505)			
Outstanding at September 30, 2021	2,059,453	$ 11.00	5.34	$ 589
Exercisable at September 30, 2021	1,733,441	$ 11.93	4.66	$ 487

The total intrinsic value of stock options exercised was insignificant for the nine months ended September 30, 2021.

Restricted Stock Units

A summary of RSU activity for the nine months ended September 30, 2021 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2020	3,393,425	$ 4.41
Granted	3,748,175	6.87
Released	(1,131,097)	5.00
Forfeited	(333,393)	5.44
Unvested balance at September 30, 2021	5,677,110	$ 5.85

Total unrecognized stock-based compensation expense for all stock-based awards was $17.7 million as of September 30, 2021. This amount will be recognized over a weighted-average period of 2.07 years.

2009 Employee Stock Purchase Plan

In June 2009, at the annual meeting of stockholders, the stockholders of the Company approved the 2009 Employee Stock Purchase Plan, or the 2009 ESPP. As of September 30, 2021, 36,539 shares were available for issuance under the 2009 ESPP. Since the merger involving privately-held Paratek Pharmaceuticals, Inc. and Transcept Pharmaceuticals, Inc., the Company has not made the 2009 ESPP available to employees.

2018 Employee Stock Purchase Plan

The Company's Board of Directors adopted, and in June 2018 Company's stockholders approved, the Paratek Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan, or the 2018 ESPP. The 2018 ESPP was amended in October 2018 to change the commencement dates of the offering periods. The maximum aggregate number of shares of the Company's common stock that may be purchased under the 2018 ESPP is 943,294 shares, or the ESPP Share Pool, subject to adjustment as provided for in the 2018 ESPP. The 2018 ESPP allows eligible employees to purchase shares during certain offering periods, which will be six-month periods commencing June 1 and ending November 30 and commencing December 1 and ending May 31 of each year. The first offering under the 2018 ESPP occurred on December 1, 2018. During the nine months ended September 30, 2021, the Company issued 63,920 shares of common stock with proceeds of $0.4 million. As of September 30, 2021, 506,357 shares remain available for issuance under the 2018 ESPP. During the nine months ended September 30, 2021, the Company recognized an insignificant amount in related stock-based compensation expense.

Revenue Performance Incentive Plan

On October 4, 2018, the Company adopted the Revenue Performance Incentive Plan, or the Plan, to grant performance-based cash incentive awards to key employees and consultants of the Company. The Plan provides for an incentive pool of up to $50.0 million, plus accrued interest during the period between the awards' vesting date and payment dates. Each participant will be allocated a percentage of the incentive pool.

The incentive pool will be divided into two equal tranches with the first tranche vesting upon the Company's achievement of cumulative net product revenues over $300.0 million by December 31, 2025, or Tranche 1, and the second tranche vesting upon the Company's achievement of cumulative product revenues over $600.0 million by December 31, 2026, or Tranche 2. Participants will vest annually in each tranche of their awards in four equal installments on December 31, 2019, December 31, 2020, December 31, 2021, and December 31, 2022, subject to their continued employment with the Company through the applicable vesting date. If a participant's employment terminates prior to December 31, 2022 due to death or disability, the participant will automatically vest in an additional 25% of each tranche of his or her award. Upon the achievement of a Tranche 1 or Tranche 2 milestone (but not a deemed achievement in connection with a change of control), each participant who has remained in continuous employment with the Company through December 31, 2022 will be 100% vested in the applicable tranche. In the event of a change of control of the Company prior to December 31, 2026, participants whose employment has terminated prior to such date will be eligible for payouts under the Plan based on the then-vested portion of their awards, and participants who have remained employed through the change of control will be deemed to have time vested in full in each tranche of their awards.

Upon the achievement of a Tranche 1 or Tranche 2 milestone (but not a deemed achievement in connection with a change of control), each participant's payout in respect of the applicable tranche of his or her award will equal (a) the participant's then-vested percentage, multiplied by (b) $25 million, multiplied by (c) the participant's individual percentage allocation of the incentive pool.

If a change of control occurs prior to December 31, 2026, and the Tranche 1 milestone was not achieved prior to the change of control, the Tranche 1 milestone will be deemed to be achieved at a percentage equal to the greater of (1) 50% and (2) the cumulative product revenues as of the change of control, divided by $300.0 million. If a change of control occurs prior to December 31, 2026, and the Tranche 2 milestone was not achieved prior to the change of control, the Tranche 2 milestone will be deemed to be achieved at a percentage equal to the greater of (1) 30% and (2) the cumulative product revenues as of the change of control, divided by $600.0 million. A participant's payout in respect of each tranche of his or her award in a change of control will equal (1) the participant's then-vested percentage of such tranche, multiplied by (2) the percentage of that tranche's milestone that has been achieved or is deemed to have been achieved, multiplied by (3) $25.0 million, multiplied by (4) the participant's individual percentage allocation of the incentive pool.

Amounts that become payable upon achievement of the Tranche 1 milestone will be paid in a lump-sum in the first quarter of 2026 and amounts that become payable upon achievement of the Tranche 2 milestone will be paid in a lump-sum in the first quarter of 2027. In the event of a change of control, any portion of the incentive pool that is earned, but unpaid, or deemed earned in connection with the change of control will be paid at the time of the change of control.

If a change of control occurs prior to the achievement of either or both of the Tranche 1 and Tranche 2 milestones, the awards will remain outstanding and the remaining unpaid portion of the incentive pool applicable to the Tranche 1 or Tranche 2 milestone, as applicable, will be paid following the achievement of either such milestone at the time or times the bonuses would otherwise be paid out. Any successor in interest to the Company upon or following a change of control will be required to assume all obligations under the Plan.

Awards may be paid out in cash or in a combination of cash and registered securities of equal value (based on the Company's 20-day trailing average closing common stock price), with the portion paid in registered securities not to exceed 50% of the aggregate payment amount with respect to each tranche; provided, however, that any amounts payable with respect to an award in connection with a change in control will be paid in cash.

The Company will recognize the compensation cost over the requisite service period, to the extent achievement of the performance condition is deemed probable relative to targeted performance. The performance condition is not yet deemed probable; as such, no amounts were accrued under the Plan during the nine months ended September 30, 2021.

13. Long-Term Debt

R-Bridge Loan Agreement

On December 31, 2020, or the Closing Date, the Company, through its wholly-owned subsidiary PRTK SPV2 LLC, a Delaware limited liability company, or the Subsidiary, entered into a royalty and revenue interest-backed loan agreement, or the R-Bridge Loan Agreement, with an affiliate of R-Bridge Healthcare Investment Advisory, Ltd., or the R-Bridge Lender. Pursuant to the terms of the R-Bridge Loan Agreement, the Subsidiary borrowed a $60.0 million term loan, secured by, and repaid with proceeds from, (i) royalties from the Zai Collaboration Agreement, or the Royalty Interest, and (ii) a revenue interest based on the Company's U.S. sales of NUZYRA in an initial amount of two and a half percent (2.5%), which amount may adjust under certain circumstances up to five percent (5%), of the Company's net U.S. sales, subject to an annual cap of $10.0 million, which may adjust under certain circumstances to $12.0 million, or the Revenue Interest.

Under the R-Bridge Loan Agreement, the outstanding principal balance will bear interest at an annual rate of 7.0%, increasing to an annual rate of 10% during the continuance of any event of default. Payments of the obligations outstanding under the R-Bridge Loan Agreement are made quarterly and began with the payment due in respect of the quarter ended March 31, 2021, out of the Royalty Interest payments and Revenue Interest payments received by the Subsidiary during such quarter, or the Collection Amount. On each payment date, after payment of certain expenses, the Collection Amount shall be applied first to accrued interest, with any excess up to $15.0 million per annum applied to repay principal until the balance is fully repaid, and any shortfalls being capitalized and added to the principal balance of the loan. Amounts in excess of the $15.0 million annual cap shall be shared between the Company and the R-Bridge Lender based on a formula set out in the R-Bridge Loan Agreement. Following repayment in full of the loan, the first $15.0 million per annum in Collection Amount shall be paid to the Company and any amounts in excess shall be shared between the Company and the R-Bridge Lender based on a formula set out in the R-Bridge Loan Agreement.

Prior to the eighth (8th) anniversary of the Closing Date, the R-Bridge Loan Agreement will automatically terminate once the Subsidiary has paid to the R-Bridge Lender, in the form of regularly scheduled payments or as a voluntary prepayment, a capped amount of $114.0 million, less principal, interest and certain fee payments through the date of such prepayment, or the Capped Amount. From and after the eighth (8th) anniversary of the Closing Date, the Revenue Interest can be terminated by payment of the Capped Amount, but the Royalty Interest payments shall continue until maturity of the R-Bridge Loan Agreement on December 31, 2032, at which time, the outstanding principal amount of the loan, if any, together with any accrued and unpaid interest, and all other obligations then outstanding, shall be due and payable in cash by the Subsidiary.

The Company's subsidiary, PRTK SPV1 LLC, a Delaware limited liability company and owner of the Subsidiary's capital stock, has entered into a Pledge and Security Agreement in favor of the R-Bridge Lender, pursuant to which the Subsidiary's obligations under the R-Bridge Loan Agreement are secured by PRTK SPV1 LLC's pledge of all of the Subsidiary's capital stock.

The R-Bridge Loan Agreement contains certain customary affirmative covenants, including those relating to: use of proceeds; maintenance of books and records; financial reporting and notification; compliance with laws; and protection of Company intellectual property. The R-Bridge Loan Agreement also contains certain customary negative covenants, barring the Subsidiary from: certain fundamental transactions; issuing dividends and distributions; incurring additional indebtedness outside of the ordinary course of business; engaging in any business activity other than related to the Zai Collaboration Agreement; and permitting any additional liens on the collateral provided to the R-Bridge Lender under the R-Bridge Loan Agreement. As of September 30, 2021, the Company was in compliance with all covenants under the R-Bridge Loan Agreement.

An ancillary agreement executed by the Company and the Subsidiary in respect of the Revenue Interest, contains negative covenants applicable to the Company, including restrictions on the sale or transfer of our assets related to NUZYRA and giving rise to the Revenue Interest, each subject to the exceptions set forth therein.

The R-Bridge Loan Agreement contains customary defined events of default, upon which any outstanding principal, unpaid interest, and other obligations of the Subsidiary, shall be immediately due and payable by the Subsidiary. These include: failure to pay

any principal or interest when due; failure to the Capped Amount as and when due following a non-qualified change of control of the Company, any uncured breach of a representation, warranty or covenant; any uncured failure to perform or observe covenants; any uncured breach of our representations, warranties or covenants under an ancillary agreement executed by the Company and the Subsidiary in respect of the Royalty Interest; any termination of the Zai Collaboration Agreement; and certain bankruptcy or insolvency events. No events of default had occurred under the R-Bridge Loan Agreement through September 30, 2021.

The Company raised approximately $58.3 million in net proceeds in connection with the R-Bridge Loan Agreement, comprised of the $60.0 million term loan funded at execution, net of $1.1 million in lender fees accounted for as debt discount and $0.6 million in direct and incremental third-party expenses accounted for as debt issuance costs. The net proceeds of the term loan, together with cash on hand, was used to prepay in full all obligations outstanding under the Amended and Restated Loan and Security Agreement dated as of June 27, 2019, as amended, with Hercules Technology III, L.P., certain other lenders and Hercules Capital, Inc. (as agent), or the Hercules Loan Agreement.

The Company evaluated the R-Bridge Loan Agreement for embedded derivatives pursuant to ASC 815, *Derivatives and Hedging* (ASC 815). The Company determined that the R-Bridge Loan Agreement represents a debt host due to its legal form. The Company concluded that the contingent put options that could require mandatory repayment upon the occurrence of an event of default, change of control, and certain other events are required to be bifurcated from the debt host instrument and accounted for separately as derivative instruments. Such features are not clearly and closely related to the debt host contract and a separate instrument with the same terms would be considered a derivative instrument subject to the requirements of ASC 815. However, the Company has determined that the fair value of these embedded derivatives is nominal at September 30, 2021 and December 31, 2020 due to the estimated likelihood of the any of the associated events occurring. All other embedded features are not required to be accounted for separately because they are either clearly and closely related to the debt host instrument or qualify for a scope exception from ASC 815.

The accounting for the R-Bridge Loan Agreement requires the Company to make certain estimates and assumptions, particularly about future royalties under the Zai Collaboration Agreement and sales of NUZYRA in the U.S. Such estimates and assumptions are utilized in determining the expected repayment term, amortization period of the debt discount and issuance costs, accretion of interest expense and classification between current and long-term portions of amounts outstanding. The Company amortizes the debt discount and issuance costs to interest expense over the expected term of the arrangement using the interest method based on projected cash flows. Similarly, the Company classifies as current debt for the R-Bridge Loan Agreement, amounts that are expected to be repaid during the succeeding twelve months after the reporting period end. However, the repayment of amounts due under the R-Bridge Loan Agreement is variable because the cash flows to be utilized for periodic payments is a function of amounts received by the Company with respect to the Royalty Interest and the Revenue Interest. Accordingly, the estimates of the magnitude and timing of amounts to be available for debt service are subject to significant variability and thus, subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change, which may result in future adjustments to the portion of the debt that is classified as a current liability, the amortization of debt discount and issuance costs and the accretion of interest expense.

The amount of principal to be repaid in each of the five succeeding years is not fixed and determinable.

Other amounts that may become due and payable under the R-Bridge Loan Agreement, including amounts shared between the parties with respect to cash flows received in excess of pre-defined thresholds, are recognized as additional interest expense when they become probable and estimable.

The following table summarizes the impact of the R-Bridge Loan Agreement on the Company's condensed consolidated balance sheets at September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Principal debt including paid-in-kind interest	$ 60,961	$ 60,000
Unamortized debt discount and issuance costs	(1,516)	(1,680)
Carrying value	$ 59,445	$ 58,320

During the nine months ended September 30, 2021, $1.0 million of paid-in-kind interest was capitalized and added to the principal balance of the loan, which represents the shortfall between the interest owed and the Collection Amount.

The Company recognized interest expense of $1.1 million and $3.4 million, and an insignificant amount of amortization expense on the debt issuance costs, on the R-Bridge Loan Agreement for the three and nine months ended September 30, 2021, respectively.

Convertible Senior Subordinated Notes

On April 18, 2018, the Company entered into a Purchase Agreement, or the Purchase Agreement, with several initial purchasers, or the Initial Purchasers, for whom Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as representatives, relating to the sale of $135.0 million aggregate principal amount of 4.75% Convertible Senior Subordinated Notes due 2024, or the Notes, to the Initial Purchasers. The Company also granted the Initial Purchasers an option to purchase up to an additional $25.0 million aggregate principal amount of Notes, which was exercised in full on April 20, 2018.

The Purchase Agreement includes customary representations, warranties and covenants. Under the terms of the Purchase Agreement, the Company agreed to indemnify the Initial Purchasers against certain liabilities.

In addition, J. Wood Capital Advisors LLC, the Company's financial advisor, purchased $5.0 million aggregate principal amount of Notes in a separate, concurrent private placement on the same terms as other investors.

The Notes were issued by the Company on April 23, 2018, pursuant to an Indenture, dated as of such date, or the Indenture, between the Company and U.S. Bank National Association, as trustee, or the Trustee. The Notes bear cash interest at the annual rate of 4.75%, payable on November 1 and May 1 of each year, beginning on November 1, 2018, and mature on May 1, 2024 unless earlier repurchased, redeemed or converted. The Company will settle conversions of the Notes through delivery of shares of common stock of the Company, in accordance with the terms of the Indenture. The initial conversion rate for the Notes is 62.8931 shares of common stock (subject to adjustment as provided for in the Indenture) per $1,000 principal amount of the Notes, which is equal to an initial conversion price of approximately $15.90 per share, representing a conversion premium of approximately 20% above the closing price of the common stock of $13.25 per share on April 18, 2018.

Holders of the Notes may convert all or any portion of their Notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the second scheduled trading day immediately preceding the stated maturity date.

The Company may redeem for cash all or part of the Notes, at its option, on or after May 6, 2021, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If the Company experiences a fundamental change, as described in the Indenture, prior to the maturity date of the Notes, holders of the Notes will, subject to specified conditions, have the right, at their option, to require the Company to repurchase for cash all or a portion of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change repurchase date. In addition, following certain corporate events that occur prior to the maturity date of the Notes and following a notice of redemption of the Notes, the Company will increase the conversion rate for a holder who elects to convert its Notes in connection with such corporate event or redemption.

The Indenture provides for customary events of default. In the case of an event of default with respect to the Notes arising from specified events of bankruptcy or insolvency, all outstanding Notes will become due and payable immediately without further action or notice. If any other event of default with respect to the Notes under the Indenture occurs or is continuing, the Trustee or holders of at least 25% in aggregate principal amount of the then outstanding Notes may declare the principal amount of the Notes to be immediately due and payable.

After deducting costs incurred of $6.0 million, the Company raised net proceeds from the issuance of long-term convertible debt of $159.0 million in April 2018. All costs were deferred and are being amortized over the life of the Notes at an effective interest rate of 5.47% and recorded as additional interest expense.

The Company has evaluated the Indenture for derivatives pursuant to ASC 815, *Derivatives and Hedging*, or ASC 815, and identified an embedded derivative that requires bifurcation as the feature is not clearly and closely related to the host instrument. The embedded derivative is a default provision, which could require additional interest payments. The Company determined in the prior year that the fair value of this embedded derivative was nominal.

The Company evaluated the conversion feature and determined it was not within the scope of ASC 815 and therefore is not required to be accounted for separately. The Company concluded that the embedded conversion option is not subject to separate accounting pursuant to either the cash conversion guidance or the beneficial conversion feature guidance. Under the general conversion guidance in ASC 470, *Debt*, all of the proceeds received from the Notes was recorded as a liability on the condensed consolidated balance sheet.

The following table summarizes the impact of the Notes on the Company's condensed consolidated balance sheets at September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Principal debt	$ 165,000	$ 165,000
Unamortized debt issuance costs	(2,829)	(3,578)
Carrying value	$ 162,171	$ 161,422

The Company recognized coupon interest expense of $2.0 million and $5.9 million, and amortization expense on the debt issuance costs of $0.2 million and $0.7 million, on the Notes for the three and nine months ended September 30, 2021, respectively.

Royalty-Backed Loan Agreement

On February 25, 2019, the Company, through its wholly-owned subsidiary Paratek Royalty Corporation, or the Subsidiary, entered into the Royalty-Backed Loan Agreement with HCRP. Pursuant to the terms of the Royalty-Backed Loan Agreement, upon the satisfaction of the conditions precedent set forth therein, the Subsidiary borrowed a $32.5 million loan, which was secured by, and will be repaid based upon, royalties from the Almirall Collaboration Agreement. On May 1, 2019, the Company received $27.8 million, net of $0.5 million lender discount, $0.2 million in lender expenses incurred, and $4.0 million that was deposited into an interest reserve account. The Company also paid $1.2 million in other lender fees related to the Royalty-Backed Loan Agreement.

Under the Royalty-Backed Loan Agreement, the outstanding principal balance will bear interest at an annual rate of 12.0%. Payments of interest under the Royalty-Backed Loan Agreement are made quarterly out of the Almirall Collaboration Agreement royalty payments received since the immediately preceding payment date. On each interest payment date, any royalty payments in excess of accrued interest on the loan will be used to repay the principal of the loan until the balance is fully repaid and any royalty shortfalls will be capitalized and added to the principal balance of the loan. In addition, the Subsidiary made up-front payments to HCRP of (i) a 1.5% fee and (ii) up to $300,000 for HCRP's expenses. The Royalty-Backed Loan Agreement matures on May 1, 2029, at which time, if not earlier repaid in full, the outstanding principal amount of the loan, together with any accrued and unpaid interest, and all other obligations then outstanding, shall be due and payable in cash. The Company has entered into a Pledge and Security Agreement in favor of HCRP, pursuant to which the Subsidiary's obligations under the Royalty-Backed Loan Agreement are secured by a pledge of all of the Company's holdings of the Subsidiary's capital stock.

The Royalty-Backed Loan Agreement contains certain customary affirmative covenants, including those relating to: use of proceeds; maintenance of books and records; financial reporting and notification; compliance with laws; and protection of Company intellectual property. The Royalty-Backed Loan Agreement also contains certain customary negative covenants, barring the Subsidiary from: certain fundamental transactions; issuing dividends and distributions; incurring additional indebtedness outside of the ordinary course of business; engaging in any business activity other than related to the Almirall Collaboration Agreement; and permitting any additional liens on the collateral provided to HCRP under the Royalty-Backed Loan Agreement.

The Royalty-Backed Loan Agreement contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be immediately due and payable. These include: failure to pay any principal or interest when due; any uncured breach of a representation, warranty or covenant; any uncured failure to perform or observe covenants; any uncured cross default under a material contract; any uncured breach of the Company's representations, warranties or covenants under its Contribution and Servicing Agreement with the Subsidiary; any termination of the Almirall Collaboration Agreement; and certain bankruptcy or insolvency events.

The following table summarizes the impact of the Royalty-Backed Loan Agreement on the Company's condensed consolidated balance sheets at September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Principal debt including paid-in-kind interest	$ 33,340	$ 32,500
Unamortized debt issuance costs	(1,687)	(1,768)
Carrying value	$ 31,653	$ 30,732

During the nine months ended September 30, 2021, $0.8 million of paid-in-kind interest was capitalized and added to the principal balance of the loan, which represents the shortfall between the interest owed, payments made from the interest reserve account, which was exhausted in May 2021, and the Almirall Collaboration Agreement royalty payments received.

The Company recognized interest expense of $1.0 million and $2.9 million and an insignificant amount of amortization expense on the debt issuance costs on the Royalty-Backed Loan Agreement for the three and nine months ended September 30, 2021, respectively.

Debt issuance costs are presented on the consolidated balance sheet as a direct deduction from the related debt liability rather than capitalized as an asset in accordance with ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*.

Long-term debt on the Company's consolidated balance sheets at September 30, 2021 and December 31, 2020 includes the carrying value of the R-Bridge Loan Agreement, the Notes and the Royalty-Backed Loan Agreement.

14. Leases

Operating Leases

The Company leases its Boston, Massachusetts and King of Prussia, Pennsylvania office spaces under non-cancelable operating leases expiring in 2023 and 2024, respectively.

The Company executed an amendment to the existing lease agreement on its Boston office space in April 2021. The amended lease agreement released 8,104 rentable square feet of office space and extends the lease term for the remaining 4,153 rentable square feet of office space through August 2023 for an additional commitment of $0.4 million. In accordance with the amendment, the Company will be refunded the insignificant security deposit paid in July 2016.

The Company has also identified an embedded lease in its manufacturing and services agreement with CIPAN – Companhia Industrial Produtora de Antibióticos, or CIPAN, which was later amended and restated in April 2018, and further amended and restated in February 2019, December 2019, July 2020, and December 2020. For additional details relating to these agreements, refer to Note 18*, Commitments and Contingencies* of the 2020 Form 10-K.

The total operating liability is presented on the Company's condensed consolidated balance sheet based on maturity dates. $0.6 million of the total operating liabilities is classified under "other current liabilities" for the portion due within twelve months, and $1.4 million is classified under "long-term lease liability".

15. Income Taxes

The Company recorded no provision for income taxes for the three or nine months ended September 30, 2021 and September 30, 2020.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against the Company's otherwise recognizable net deferred tax assets.

16. Product Revenue

To date, the Company's only source of product revenue has been from NUZYRA product sales beginning in February 2019 when NUZYRA was launched in the U.S. The following table summarizes balances and activity in each of the product revenue allowance and reserve categories (in thousands):

	Chargebacks, discounts and fees	Government and other rebates	Returns	Patient assistance	Total
Balance at December 31, 2020	$ 627	$ 2,202	$ 386	$ 214	$ 3,429
Provision related to current period sales	3,268	9,686	1,164	435	14,553
Adjustment related to prior period sales	(147)	(384)	(615)	—	(1,146)
Credit or payments made during the period	(2,895)	(7,663)	(136)	(417)	(11,111)
Balance at September 30, 2021	$ 853	$ 3,841	$ 799	$ 232	$ 5,725

17. Commitments and Contingencies

In the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of September 30, 2021, the Company was not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on the Company's financial position. No governmental proceedings are pending or, to the Company's knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of executive management or affiliate of the Company is either a party adverse to the Company or the Company's subsidiaries or has a material interest adverse to the Company or the Company's subsidiaries.

On July 14, 2021, the Company entered into a supply agreement with CARBOGEN AMCIS AG, or Carbogen, that provides for the terms and conditions under which Carbogen will manufacture and supply to the Company the active pharmaceutical ingredient for the Company's omadacycline product in bulk quantities, or the Carbogen Product. Under this agreement, the Company is responsible for the cost and supply of crude omadacycline that Carbogen requires to manufacture the Carbogen Product and perform related services. The Company is obligated to initially pay Carbogen an amount in the high six-digit U.S. dollar range per batch of Carbogen Product that the Company orders, and the price may be adjusted in accordance with the terms of the agreement. The Company may also request that Carbogen perform certain services related to the Carbogen Product, for which the Company will pay reasonable compensation to Carbogen.

18. Recent Accounting Pronouncements

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 its financial position or results of operations upon adoption.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2023. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. Based on the composition of our investment portfolio, accounts receivable and other financial assets, current market conditions and historical credit loss activity, the adoption of these standards is not expected to have a material effect on the Company's consolidated balance sheet, consolidated statements of operation and comprehensive loss and related disclosures.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q. All references to "Paratek," "we," "us," "our" or the "Company" in this Quarterly Report on Form 10-Q mean Paratek Pharmaceuticals, Inc. and our subsidiaries.

This discussion contains certain forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potential," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward- looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the U.S. Securities and Exchange Commission, or the SEC, on March 29, 2021, or the 2020 Form 10-K, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, as filed with the SEC on May 17, 2021, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, as filed with the SEC on August 9, 2021, and this Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and except as required by law, we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Company Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of novel life-saving therapies for life-threatening diseases or other public health threats for civilian, government and military use. Our United States, or U.S., Food and Drug Administration, or FDA, approved commercial product, NUZYRA® (omadacycline) is a once-daily oral and intravenous antibiotic for the treatment of adult patients with community-acquired bacterial pneumonia, or CABP, and acute skin and skin structure infections, or ABSSSI, caused by susceptible pathogens. SEYSARA® (sarecycline) is an FDA-approved product with respect to which we have exclusively licensed in the U.S. and the People's Republic of China, Hong Kong and Macau, or the greater China region, certain rights to Almirall, LLC, or Almirall. SEYSARA is currently being marketed by Almirall in the U.S. as a once-daily oral therapy for the treatment of moderate to severe acne vulgaris. With respect to our technology as it relates to sarecycline, we retain development and commercialization rights in all countries other than the U.S. and the greater China region, and in February 2020, we exclusively licensed from Almirall certain technology owned or in-licensed by Almirall or its affiliates that is necessary or useful to develop or commercialize sarecycline outside of the U.S. Almirall plans to develop sarecycline for acne in China, with a submission to the China National Medical Products Administration, or NMPA, according to Almirall, expected in 2023.

During the first quarter of 2021, we completed the initial phase of our plan to expand our U.S. launch of NUZYRA into the community setting based on NUZYRA's product attributes, including its once-daily oral formulation, broad reimbursement coverage and infectious disease physician support. Our expansion of commercial promotion into the community setting focused initially on ABSSSI, and broadened in the fall of 2021 to include the treatment of CABP as we received FDA approval of the oral-only loading dose regimen in the second quarter of 2021.

In December 2019, we entered into a five-year contract with an option to extend to ten years with the Biomedical Advanced Research and Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services, or HHS, Office of the Assistant Secretary for Preparedness and Response, or ASPR, herein referred to as the BARDA contract. The BARDA contract supports the development of NUZYRA for the treatment of pulmonary anthrax, FDA post-marketing requirements, or PMRs, associated with the initial NUZYRA approval, and an option for BARDA to procure up to 10,000 treatment courses of NUZYRA for use against potential biothreats. On September 27, 2021, we and BARDA modified the original BARDA contract, herein referred to as the amended BARDA contract, to provide additional funding to expand the development of NUZYRA under an FDA Animal Efficacy Rule development program to support a supplemental New Drug Application, or sNDA, to the FDA to include post-exposure prophylaxis, or PEP, in addition to the treatment of pulmonary anthrax, herein referred to as the amended option.

Under the terms of the BARDA contract, approximately $59.4 million was awarded to us by BARDA in December 2019 for the development of NUZYRA for the treatment of pulmonary anthrax and the purchase of an initial 2,500 treatment courses of NUZYRA. As part of this initial $59.4 million award, the $37.9 million procurement of NUZYRA was delivered to and accepted by

BARDA in June 2021, and the amount earned from this procurement was recognized in net U.S. sales of NUZYRA during the second quarter of 2021. We have been periodically drawing down the remaining $21.5 million of the initial award based on costs incurred during the development program.

Two additional contractual services were initiated by BARDA in April 2020 that awarded us approximately $76.8 million for reimbursement of existing FDA PMRs and approximately $20.4 million for reimbursement of manufacturing-related requirements, which we have been drawing down based on costs incurred. This additional staged funding is expected to support all FDA PMRs associated with the approval of NUZYRA, including CABP and pediatric studies, as well as a five-year post-marketing bacterial surveillance study, and support the U.S. onshoring and security requirements of our manufacturing activities for NUZYRA.

BARDA initiated the amended option in September 2021 that awarded the Company additional funding to expand the development of NUZYRA under an FDA Animal Efficacy Rule development program to support an sNDA that will include post-exposure prophylaxis, or PEP, in addition to the treatment of pulmonary anthrax for approximately $31.6 million.

The remaining awards under the amended BARDA contract include a maximum of approximately $115.3 million to provide for three additional purchases of NUZYRA anthrax treatment courses, each of which may be exercised at BARDA's discretion upon achievement of development milestones related to the anthrax treatment development program. The timing and trigger of future procurements will be linked to specific development milestones. The amended BARDA contract formalized the trigger for purchase of the second NUZYRA procurement upon BARDA's receipt of positive top-line data from our pilot efficacy treatment study of inhalation anthrax in rabbits, which we anticipate will be available in the second half of 2022.

We and BARDA also agreed under the amended contract on specific development milestones to trigger the third and fourth procurements of NUZYRA anthrax treatment courses. The third procurement will be triggered by BARDA's receipt of positive top-line data in PEP and treatment of inhalation anthrax from a combination of pilot and pivotal efficacy studies in animal models, which we anticipate will be available in 2024. The fourth procurement will be triggered by our receipt of sNDA approval from the FDA for treatment of inhalation anthrax, which we anticipate will follow the third procurement by approximately 18-24 months. We plan to provide further specificity on timelines as the anthrax development program progresses.

We have made significant progress in the pulmonary anthrax development program under the BARDA contract. A pharmacokinetic, or PK, study in rabbits was recently completed. In addition, we have evaluated minimum inhibitory concentrations, or MICs, of omadacycline against over 130 anthrax strains. Omadacycline continued to demonstrate potent MICs and is considered effective against all isolates infected with anthrax that were tested. The collection of isolates included a strain resistant to doxycycline and a strain resistant to ciprofloxacin,. Omadacycline activity remained potent and was not impacted by either of those resistant strains.

Together with BARDA, we continue to make progress advancing our efforts to onshore the manufacturing of NUZYRA to the U.S. We have completed the knowledge transfer of our manufacturing process for the active pharmaceutical ingredient, or API, of omadacycline to our U.S. onshoring partners and are currently in the development stage of the initiative. The process flow, equipment selection and facility modifications have been planned and development is expected to be completed in 2021. The manufacturing process engineering and validation is scheduled to begin in 2022, with the goal of commercial supply production in the U.S. by the end of 2023.

As part of the approval for NUZYRA, the FDA has waived the pediatric study requirement for ages 0 to < 8 years and deferred submission of pediatric studies for ages 8 to < 18 years. Specifically, the FDA has requested that we complete three pediatric studies, including a pediatric PK study followed by safety and efficacy studies in pediatric patients with both CABP and ABSSSI. In addition to pediatric requirements, as is often required for antibiotic approvals, the FDA has also required a U.S. surveillance study for five years from the date of marketing to monitor for the development of resistance to NUZYRA (omadacycline) in those organisms specific to the indications in the label. Lastly, FDA has required a second study be conducted in patients with CABP. We enrolled our first patient in this second CABP study in February 2021.

Additionally, NUZYRA was added to the Center for Disease Control and Prevention's updated report, "Antimicrobial Treatment and Prophylaxis of Plague: Recommendations for Naturally Acquired Infections and Bioterrorism Response" in July 2021. NUZYRA was added as an alternative agent for the treatment, pre-exposure prophylaxis, and postexposure prophylaxis of primary bubonic and pharyngeal plague infections in adults 18 years of age and over.

We also continue to pursue a number of other opportunities for NUZYRA. In May 2021, the FDA approved our supplemental new drug application, or sNDA, for the oral-only loading dose regimen for patients diagnosed with CABP. The sNDA included the results of a study to show that an oral-only loading dose regimen has a comparable PK profile to the approved IV loading dose regimen in patients with CABP that was established in the Phase 3 registration study.

We have discussed trial designs and potential registration pathways with the FDA to determine the efficacy and safety of omadacycline in patients afflicted with non-tuberculous mycobacteria abscessus, or NTM abscessus, which are environmental organisms that can be found in soil, dust, and water, including natural and municipal water sources. Infection occurs when a person is exposed to NTM organisms. NTM abscessus can form difficult-to-eliminate biofilms, which are collections of microorganisms that stick to each other, and adhere to surfaces in moist environments. Although severe infection can affect the lymph nodes, skin, soft tissues, bones, and joints, the vast majority of NTM abscessus infection cases are pulmonary. The diagnosis of NTM abscessus infection is often delayed due to non-specific symptoms and a lack of disease state awareness by clinicians. NTM abscessus is a rare and orphan disease with no FDA-approved therapies, which we estimate has a potential $1.0 billion addressable market in the U.S. In August 2021, FDA granted orphan drug designation for NUZYRA for the treatment of infections caused by NTM. This orphan drug designation includes NTM pulmonary disease caused by Mycobacterium abscessus complex, which is the focus of an ongoing Phase 2b study.

Start-up activities for our Phase 2b clinical study for treatment of pulmonary NTM abscessus with omadacycline are underway. This study was initiated in June 2021 with our first patient enrolled in the Phase 2b NTM study in October 2021. This study is a double-blinded, placebo-controlled, randomized monotherapy study of pulmonary NTM abscessus in patients who are not receiving other treatments. Study size will be approximately 75 subjects randomized in a 1.5 to 1 ratio. Therapy will last for 12 weeks with an efficacy endpoint assessment at that timepoint. Due to the small numbers of patients with this rare disease, we expect this study will complete enrollment within approximately two years from commencement.

To date, we have devoted a substantial amount of our resources to research and development efforts, including conducting clinical trials for omadacycline, protecting our intellectual property and providing selling, general and administrative support for these operations. We began generating revenue from product sales in February 2019; as such, we have historically financed our operations primarily through sales of our common stock, debt financings, strategic collaborations, and grant funding.

We have incurred significant losses since our inception in 1996. Our accumulated deficit at September 30, 2021 was $834.6 million and our net loss for the nine months ended September 30, 2021 was $26.8 million. A substantial amount of our net losses resulted from costs incurred in connection with our research and development programs and selling, general and administrative costs associated with our operations. The net losses and negative operating cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate offsetting revenue. We expect to continue to incur significant expenses and operating losses for the next several years.

While our BARDA contract is expected to significantly strengthen our cash position, unless we can generate a sufficient amount of revenue from our commercial products, we may need to raise additional capital in order to support and accelerate the commercialization of omadacycline and to advance the development of our other indications for omadacycline, such as NTM, or other product candidates. If we cannot generate a sufficient amount of product or royalty revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of public or private equity offerings, debt or other structured financings, strategic collaborations, grant funding and government funding. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our development programs or commercialization efforts. We will need to generate significant revenue to achieve and sustain profitability, and we may never be able to do so.

Business Update Regarding COVID-19

The COVID-19 pandemic continues to present a substantial public health and economic challenge around the world and is continuing to affect our employees, health care institutions, patients, communities and business operations, as well as the U.S. economy and financial markets. The COVID-19 related restrictions on in-person promotional access to health care institutions and the overall impact of COVID-19 restrictions on the health care and hospital environments could restrict the full potential of NUZYRA's growth. The length of time and full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including the duration, spread and severity of the outbreak, new information that may emerge concerning COVID-19, any resurgence of COVID-19 cases, including as a result of variant strains of the underlying virus, the actions taken to contain the virus or treat its impact, the availability and efficacy of vaccines against COVID-19 and the economic impact on local, regional, national and international markets.

To date, we and our partners have been able to continue to supply our products to our patients worldwide and currently do not anticipate any interruptions in supply for the foreseeable future. We continue to assess the potential impact of the COVID-19 pandemic on our three clinical studies that have begun or will soon begin, our BARDA anthrax development program, as well as on our business and operations, including our sales, expenses, supply chain and other clinical studies.

Our office-based employees have been working from home since early March 2020. We suspended in-person interactions by our customer-facing personnel in healthcare settings during the majority of the second quarter of 2020. During this period of suspended in-person interactions, we engaged with our customers remotely in an effort to continue to support and educate healthcare professionals. In late June 2020, our customer-facing personnel began re-engaging with our customers in a manner consistent with guidance issued by the Centers for Disease Control and Prevention and other state and local mandates. Our customer-facing personnel are now operating through a hybrid model of both virtual and in-person engagement.

Our third-party contract manufacturing partners continue to operate their manufacturing facilities at or near normal levels. While we currently do not anticipate any interruptions in our supply chain, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our and/or our third-party suppliers' and contract manufacturing partners' ability to manufacture our products or the products of our partners. The COVID-19 pandemic has prevented technical service, quality assurance and supply operations personnel from traveling to our third-party contract manufacturing partners in Europe.

For additional information on the various risks posed by the COVID-19 pandemic, refer to Item 3. *Quantitative and Qualitative Disclosures About Market Risk* and Item 1A. *Risk Factors* included in the 2020 Form 10-K.

Financial Operations Overview

Product Revenue, Net

Product revenue, net, is recognized when earned on sales of NUZYRA, which was approved by the FDA in October 2018 and launched in the U.S. in February 2019. NUZYRA is sold principally to a limited number of specialty distributors and specialty pharmacy providers in the U.S. These customers subsequently resell our product to health care providers or dispense the product to patients. In addition to distribution agreements with customers, we enter into arrangements with health care providers and payers that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of our product. Product revenue is recognized net of reserves for all variable consideration, including rebates, chargebacks, discounts and product returns.

Under the terms of the BARDA contract, BARDA can procure up to 10,000 anthrax treatment courses of NUZYRA.. As of September 30, 2021, an initial 2,500 treatment courses of NUZYRA were purchased by BARDA. The product procurement performance obligations generate revenue at a point in time, which will be upon transfer of control of the product. As such, the related revenue for these performance obligations is recognized at a point in time as product revenue within our consolidated statement of operations. Refer to Note 7, *Government Contract Revenue* to the interim condensed consolidated financial statements included in this report for further discussion of the BARDA contract and related revenue recognition.

Government Contract Service Revenue

Government contract service revenue is recognized when earned under our BARDA contract and represents the reimbursement by BARDA of costs incurred by us for work performed to develop NUZYRA for the treatment of pulmonary anthrax and for the U.S. onshoring of NUZYRA manufacturing plus a small fixed administrative fee. Refer to Note 7, *Government Contract Revenue* to the interim condensed consolidated financial statements included in this report for further discussion of the BARDA contract and related revenue recognition.

Government Contract Grant Revenue

The allocated consideration of government contract grant revenue is recognized when earned under our BARDA contract and represents the reimbursement by BARDA of costs incurred by us for FDA post-marketing requirements, or PMRs, associated with the approval of NUZYRA, including CABP and pediatric studies, as well as a five-year post-marketing bacterial surveillance study. Refer to Note 7, *Government Contract Revenue* to the interim condensed consolidated financial statements included in this report for further discussion of the BARDA contract and related revenue recognition.

Collaboration and Royalty Revenue

Collaboration and royalty revenue are recognized when revenue earned under our collaboration and license agreements. Refer to Note 8, *License and Collaboration Agreements* to the interim condensed consolidated financial statements included in this report for further discussion of the collaboration agreements and the related revenue recognition.

Cost of Product Revenue

Cost of product revenue represents the cost of the product itself, labor and overhead, and any reserve for excess or obsolete inventory, as well as stability studies, and inventory scrap. Cost of product revenue also represents royalties owed on net sales of NUZYRA.

Research and Development Expense

Research and development expenses consisted primarily of costs directly incurred by us for the development of our product candidates, which include:

- expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites that conduct our clinical trials;
- the cost of acquiring and manufacturing preclinical and clinical study materials and developing manufacturing processes;
- direct employee-related expenses, including salaries, benefits, travel and stock-based compensation expense of our research and development personnel;
- allocated facilities, depreciation, and other expenses, which include rent and maintenance of facilities, insurance and other supplies; and
- costs associated with preclinical activities and regulatory compliance.

Research and development expenses also include gross reimbursable costs incurred related to research and development services performed for the treatment of pulmonary anthrax, services performed for U.S. manufacturing onshoring and security requirements, and services performed for FDA PMRs under the BARDA contract.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our products or product candidates for which we or any partner obtain regulatory approval, such as NUZYRA and SEYSARA. Aside from the FDA approval of NUZYRA and SEYSARA in the U.S., we or our partners may never succeed in achieving regulatory approval for any of our other product candidates. The duration, costs and timing of clinical trials and development of our product candidates depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that therapeutic candidate. For example, if the FDA, or another regulatory authority, were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of the clinical development of product candidates, or if we experience significant delays in the enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We manage certain activities, such as clinical trial operations, manufacture of clinical trial material, and preclinical animal toxicology studies, through third-party contract organizations. The only costs we track by each product candidate are external costs such as services provided to us by CROs, manufacturing of preclinical and clinical drug product, and other outsourced research and development expenses. We do not assign or allocate to individual development programs internal costs such as salaries and benefits, facilities costs, lab supplies and the costs of preclinical research and studies. Our research and development expenses for omadacycline and other projects during the three and nine months ended September 30, 2021 and 2020 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Omadacycline costs	$ 5,567	$ 4,219	$ 12,540	$ 9,930
Other research and development costs	2,353	2,468	7,437	7,706
Total	$ 7,920	$ 6,687	$ 19,977	$ 17,636

Selling, General and Administrative Expense

Selling, general and administrative expenses consist principally of compensation costs associated with our contract sales force, commercial support personnel, and medical affairs professionals, as well as personnel in executive and other administrative functions. Other selling, general and administrative expenses include marketing, trade, and other commercial costs and distribution fees necessary to support the launch of NUZYRA and professional fees for legal, consulting and accounting services.

Interest Income

Interest income represents interest earned on our money market funds and marketable securities.

Interest Expense

Interest expense represents interest incurred on the R-Bridge Loan Agreement, the Notes, and the Royalty-Backed Loan Agreement (each as defined in Note 13, *Long-Term Debt* to the interim condensed consolidated financial statements), as well as the adjustment of our marketable securities to amortized cost.

Results of Operations

Comparison of the three months ended September 30, 2021 and 2020

(in thousands)	Three Months Ended September 30, 2021	2020	$ Change
Product revenue, net	$ 19,432	$ 10,895	$ 8,537
Government contract service revenue	1,467	785	682
Government contract grant revenue	3,011	1,866	1,145
Collaboration and royalty revenue	537	113	424
Net revenue	$ 24,447	$ 13,659	$ 10,788
Expenses:			
Cost of product revenue	4,289	2,017	2,272
Research and development	7,920	6,687	1,233
Selling, general and administrative	25,955	20,902	5,053
Total operating expenses	38,164	29,606	8,558
Income (loss) from operations	(13,717)	(15,947)	2,230
Other income and expenses:			
Interest income	25	280	(255)
Interest expense	(4,367)	(5,178)	811
Other gains (losses), net	(143)	(10)	(133)
Net income (loss)	$ (18,202)	$ (20,855)	$ 2,653

Product Revenue, Net

Net product revenue recognized on sales of NUZYRA in the U.S. was $19.4 million and $10.9 million for the three months ended September 30, 2021 and September 30, 2020, respectively. The increase in net product revenue is primarily the result of an increase in sales volume due to higher customer demand.

Government Contract Service Revenue

Government contract service revenue earned under our BARDA contract was $1.5 million and $0.8 million for the three months ended September 30, 2021 and September 30, 2020, respectively. The increase in government contract service revenue is primarily the result of increased costs incurred for the U.S. onshoring of NUZYRA manufacturing.

Government Contract Grant Revenue

Government contract grant revenue earned under our BARDA contract was $3.0 million and $1.9 million during the three months ended September 30, 2021 and September 30, 2020, respectively. The increase in government contract service revenue is primarily the result of increased costs incurred to support existing FDA PMRs.

Collaboration and Royalty Revenue

Collaboration and royalty revenue were $0.5 million and $0.1 million for the three months ended September 30, 2021 and September 30, 2020, respectively. Royalty revenue recognized for sales of SEYSARA in the U.S. was estimated using third-party data and an approximation of discounts and allowances to calculate net product sales, to which we then applied the applicable royalty percentage specified in the Almirall Collaboration Agreement. Differences between actual and estimated royalty revenue will be adjusted in the period in which they become known, which is expected to be the following quarter.

Cost of Product Revenue

Cost of product revenue was $4.3 million for the three months ended September 30, 2021, compared to $2.0 million for the three months ended September 30, 2020. The $2.3 million increase is primarily the result of an increase in NUZYRA product sales, an increase in royalties owed on net sales of NUZYRA and delivery of sample shipments. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of NUZYRA units recognized as revenue during the three months ended September 30, 2021 were expensed prior to FDA approval in October 2018, and therefore are not included in cost of product revenue during the period. We expect cost of product revenue to increase in absolute dollars as product revenue increases.

Research and Development Expense

Research and development expenses were $7.9 million for the three months ended September 30, 2021, compared to $6.7 million for the three months ended September 30, 2020. The increase in research and development expenses was primarily due to an increase in the costs for FDA PMRs associated with the approval of NUZYRA, which are fully reimbursed under the amended BARDA contract. The remaining increase is mainly the result of start-up costs incurred for the Phase 2b NTM study.

We anticipate an increase in research and development expenses in future periods as we continue development of NUZYRA for the treatment of and PEP against pulmonary anthrax, continue the work on our FDA PMRs, and continue the onshoring of our manufacturing process, the majority of which is reimbursable under the BARDA contract. We will also incur additional spend as we continue exploring pathways for NTM indications.

Selling, General and Administrative Expense

Selling, general and administrative expenses were $26.0 million for the three months ended September 30, 2021, compared to $20.9 million for the three months ended September 30, 2020. The $5.1 million increase is primarily the result of costs incurred for the NUZYRA community expansion.

We anticipate an increase in selling, general and administrative expenses in support of our expansion into the community setting and other commercial activities, as well as the continued costs of operating as a public company. These increases will likely include costs for travel, in-person training events and sales meetings, the hiring of additional personnel, executing marketing and promotional programs, and engaging consultants, legal and other professional fees, and other operating expenses.

Other Income and Expenses

Interest expense for the three months ended September 30, 2021 represents interest incurred on the Notes of $2.2 million, R-Bridge Loan Agreement of $1.1 million, and the Royalty-Backed Loan Agreement of $1.0 million.

Interest expense for the three months ended September 30, 2020 represents interest incurred on the Hercules Loan Agreement (as defined in Note 13, *Long-Term Debt* to the interim condensed consolidated financial statements) of $1.9 million, the Notes of $2.2 million, and the Royalty-Backed Loan Agreement of $1.0 million. Interest income for the three months ended September 30, 2020 represents interest earned on our money market funds and marketable securities.

Comparison of the nine months ended September 30, 2021 and 2020

	Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**$ Change**
Product revenue, net	$ 85,441	$ 26,330	$ 59,111
Government contract service revenue	4,553	1,560	2,993
Government contract grant revenue	6,712	2,303	4,409
Collaboration and royalty revenue	1,659	710	949
Net revenue	$ 98,365	$ 30,903	$ 67,462
Expenses:			
Cost of product revenue	16,817	5,724	11,093
Research and development	19,977	17,636	2,341
Selling, general and administrative	75,420	65,514	9,906
Total operating expenses	112,214	88,874	23,340
Loss from operations	(13,849)	(57,971)	44,122
Other income and expenses:			
Interest income	61	1,347	(1,286)
Interest expense	(13,019)	(14,974)	1,955
Other gains (losses), net	(24)	67	(91)
Net loss	$ (26,831)	$ (71,531)	$ 44,700

Product Revenue, Net

Net product revenue recognized on sales of NUZYRA in the U.S. was $85.4 million and $26.3 million for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase in net product revenue is primarily the result of the delivery and acceptance of the first procurement under the BARDA contract of $37.9 million and an increase in sales volume due to higher customer demand.

Government Contract Service Revenue

Government contract service revenue earned under our BARDA contract was $4.5 million and $1.6 million for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase in government contract service revenue is primarily the result of increased costs incurred for the U.S. onshoring of NUZYRA manufacturing that began in April 2020.

Government Contract Grant Revenue

Government contract grant revenue earned under our BARDA contract was $6.7 million and $2.3 million for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase in government contract service revenue is primarily the result of increased costs incurred to support existing FDA PMRs that began in April 2020.

Collaboration and Royalty Revenue

Collaboration and royalty revenue was $1.7 million and $0.7 million for the nine months ended September 30, 2021 and September 30, 2020, respectively. Royalty revenue recognized for sales of SEYSARA in the U.S. was estimated using third-party data and an approximation of discounts and allowances to calculate net product sales, to which we then applied the applicable royalty percentage specified in the Almirall Collaboration Agreement. Differences between actual and estimated royalty revenue will be adjusted in the period in which they become known, which is expected to be the following quarter.

Cost of Product Revenue

Cost of product revenue was $16.8 million for the nine months ended September 30, 2021, compared to $5.7 million for the nine months ended September 30, 2020. The $11.1 million increase is primarily the result of the delivery and acceptance of the first procurement under the BARDA contract, an increase in NUZYRA product sales and an increase in royalties owed on net sales of NUZYRA. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of NUZYRA units recognized as revenue during the nine months ended September 30, 2021 were expensed prior to FDA approval in 2018, and therefore are not included in cost of product revenue during the period. We expect cost of product revenue to increase in absolute dollars as product revenue increases.

Research and Development Expense

Research and development expenses were $20.0 million for the nine months ended September 30, 2021, compared to $17.6 million for the nine months ended September 30, 2020. The increase in research and development expenses was primarily due to $11.3 million in costs reimbursed under the BARDA contract, which included costs for the U.S. onshoring of NUZYRA manufacturing and for FDA PMRs associated with the approval of NUZYRA. The remaining increase is mainly the result of start-up costs incurred for the Phase 2b NTM study.

We anticipate an increase in research and development expenses in future periods as we continue development of NUZYRA for the treatment of and PEP against pulmonary anthrax, continue the work on our FDA PMRs, and continue the onshoring of our manufacturing process, the majority of which is reimbursable under the BARDA contract. We will also incur additional spend as we continue exploring pathways for NTM indications.

Selling, General and Administrative Expense

Selling, general and administrative expenses were $75.4 million for the nine months ended September 30, 2021, compared to $65.5 million for the nine months ended September 30, 2020. The $9.9 million increase is primarily the result of costs incurred for the NUZYRA community expansion and an increase in stock-based compensation expense due to the probability and timing of the achievement of performance-based vesting milestones.

We anticipate an increase in selling, general and administrative expenses in support of our expansion into the community setting and other commercial activities, as well as the continued costs of operating as a public company. These increases will likely include costs for travel, in-person training events and sales meetings, the hiring of additional personnel, executing marketing and promotional programs, and engaging consultants, legal and other professional fees, and other operating expenses.

Other Income and Expenses

Interest expense for the nine months ended September 30, 2021 represents interest incurred on the Notes of $6.6 million, R-Bridge Loan Agreement of $3.4 million, and the Royalty-Backed Loan Agreement of $3.0 million.

Interest expense for the nine months ended September 30, 2020 represents interest incurred on the Hercules Loan Agreement of $5.3 million, the Notes of $6.6 million, and the Royalty-Backed Loan Agreement of $3.0 million. Interest income for the nine months ended September 30, 2020 represents interest earned on our money market funds and marketable securities.

Liquidity and Capital Resources

On May 11, 2020, we filed a registration statement on Form S-3 with the SEC, as amended on June 19, 2020 and declared effective on July 9, 2020, to sell certain of our securities in an aggregate amount of up to $250.0 million. As of October 29, 2021, $234.4 million remains available on this shelf registration statement, with $34.4 million reserved for potential sales under our Sales Agreement (as defined below).

On May 17, 2021, we entered into an At-the-Market Sales Agreement, or the Sales Agreement, with BTIG, LLC, or BTIG, under which we may offer and sell our common stock having aggregate sales proceeds of up to $50.0 million from time to time through BTIG as our sales agent. Sales of our common stock through BTIG, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including without limitation sales made directly on the Nasdaq Global Market or any other existing trading market for its common stock. BTIG will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay BTIG a commission of 3% of the gross sales proceeds of any common stock sold through BTIG under the Sales Agreement. During the nine months ended September 30, 2021, we sold 2,300,425 shares of our common stock pursuant to the Sales Agreement for $14.3 million in proceeds, after deducting an insignificant amount of commissions. As of October 29, 2021, $34.4 million remains available for sale under the Sales Agreement.

We have used and we intend to continue to use the net proceeds from offerings of our common stock and the Notes, as well as other current and retired long-term debt agreements, together with our existing capital resources and future NUZYRA product sales, government contract revenue and royalty revenue, to fund our ongoing company operations, including clinical studies of omadacycline, NUZYRA commercial operations, to expand our product portfolio, and for working capital and other general corporate purposes. Refer to Note 13, *Long-Term Debt*, for further details on our loan agreements, which include the R-Bridge Loan Agreement, the Notes, and the Royalty-Backed Loan Agreement.

As of September 30, 2021, we had cash and cash equivalents of $111.0 million.

The following table summarizes our cash provided by and used in operating, investing and financing activities:

	Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**
Net cash used in operating activities	$ (28,465)	$ (79,574)
Net cash provided by investing activities	$ 19,627	$ 65,544
Net cash provided by financing activities	$ 14,039	$ 12,216

Operating Activities

Net cash used in operating activities was $28.5 million for the nine months ended September 30, 2021, compared to $79.6 million for the nine months ended September 30, 2020. The change in net cash used in operating activities primarily consists of our net losses adjusted for non-cash items and changes in components of operating assets and liabilities as follows:

- for the nine months ended September 30, 2021, a net loss of $26.8 million was adjusted for non-cash items including stock-based compensation expense of $9.5 million and non-cash interest expense of $1.0 million and a net decrease of $12.4 million due to changes in operating assets and liabilities. The significant items in the change in operating assets and liabilities include an increase in accounts receivable, other receivables, prepaid, and other current assets of $9.4 million, offset by a decrease in inventories of $9.4 million, decrease in other liabilities and other assets of $1.5 million and a decrease in accounts payable and accrued expenses of $7.9 million.
- for the nine months ended September 30, 2020, a net loss of $71.5 million was adjusted for non-cash items including stock-based compensation expense of $7.9 million and non-cash interest expense of $5.4 million, and a net decrease of $19.3 million due to changes in operating assets and liabilities. The significant items in the change in operating assets and liabilities include an increase in accounts receivable and other current assets of $8.7 million, an increase in inventories of $7.1 million, an increase in accounts payable and accrued expenses of $3.7 million and an increase in other liabilities and other assets of $2.1 million.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2021 consists of $20.0 million in proceeds from maturities of marketable securities, offset by $0.4 million in purchases of fixed assets.

Net cash provided by investing activities during the nine months ended September 30, 2020 consists of $95.5 million in proceeds from maturities of marketable securities, offset by $29.6 million of investments in marketable securities (U.S. treasury securities) and $0.3 million in purchases of fixed assets.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2021 consists of $14.0 million in net proceeds raised through the sale of shares of our common stock under the Sales Agreement and $0.4 million in net proceeds raised through the 2018 ESPP, offset by $0.4 million in payments of debt issuance costs under the R-Bridge Loan Agreement.

Net cash provided by financing activities during the nine months ended September 30, 2020 consists of $21.9 million in net proceeds raised through the sale of shares of our common stock through the At-the-Market Sales Agreement entered into in July 2019 with Jefferies LLC and BTIG, LLC and $0.3 million in net proceeds raised through the 2018 ESPP, partially offset by the repayment of a Term Loan Tranche of $10.0 million under the Hercules Loan Agreement.

Future Funding Requirements

We began generating revenue from product sales when we launched NUZYRA in the U.S. in February 2019 and from royalties on net sales of SEYSARA in the U.S. when Almirall launched the product in January 2019. Our future funding requirements will depend on our ability to generate continued revenue from sales of NUZYRA, and our partner, Almirall's, ability to generate continued revenue from sales of SEYSARA, with respect to which we are entitled to tiered royalties in the U.S. and flat royalties in the greater China region. We do not expect to generate any other revenue unless and until our omadacycline greater China region partner, Zai, and our SEYSARA greater China region partner, Almirall, obtains regulatory approval of and commercializes its respective product in the greater China region. Zai submitted the first regulatory approval application for a licensed product in the People's Republic of China in December 2019, which was accepted by the China NMPA in February 2020 and, in April 2020, the NMPA granted priority review status for its application. We will require substantial additional funding to meet FDA PMRs for NUZYRA, which we expect to continue to be funded through the BARDA contract. Additional resources will also be needed to support and accelerate the commercialization of NUZYRA, fund the development of omadacycline in other indications, including NTM, and to advance the development of potential other product candidates, and such funding may not be available on favorable terms or at all. BARDA's procurements of NUZYRA will also be an important component to satisfying future funding requirements.

We expect to continue to incur significant expenditures and operating losses for the next few years as we:

- conduct additional clinical trials of omadacycline;
- seek regulatory approvals for additional indications for omadacycline, such as omadacycline for the treatment of NTM;
- continue to augment our sales, marketing and distribution infrastructure to commercialize NUZYRA and increase our manufacturing capacity and capabilities to satisfy demand;
- add personnel to support our planned commercialization efforts;
- build product inventory; and
- service and pay down our debt.

Based upon our current operating plan, we anticipate that our existing cash and cash equivalents of $111.0 million as of September 30, 2021 will extend our cash runway through the end of 2023 with a pathway to cash flow break even.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our pharmaceutical products, especially given the constraints on in-person promotion of NUZYRA and reduced access to prescribers due to restrictions in access to hospitals during the COVID-19 pandemic, and the unknown extent to which we will maintain existing or enter into new collaborations with third parties to participate in the development and commercialization of our product and product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that we will require to fund our continuing operations, including for our clinical development programs and commercialization efforts for NUZYRA. Our future capital requirements will depend on many factors, including:

- the progress of clinical development of omadacycline in additional indications, including NTM and pulmonary anthrax;
- the costs and timing of commercialization activities for NUZYRA;
- product revenue received from commercial sales of NUZYRA;
- royalty revenue received from commercial sales of SEYSARA by Almirall;
- timing and amount of actual reimbursements and NUZYRA purchases under the BARDA contract;
- the ability of Zai to develop, manufacture and commercialize omadacycline in the Zai territory;
- the number and characteristics of other product candidates that we may pursue;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking, obtaining, maintaining and expanding FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing and maintaining high quality sales, marketing and distribution capabilities;
- the number and characteristics of other product candidates that we may pursue;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific, commercial, operations and medical personnel;
- the effect of competing products that may limit market penetration of our products;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations;
- the economic and other terms, timing and success of our existing collaboration and licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under such arrangements; and
- the effect of the COVID-19 pandemic on the economy generally and on our business and operations specifically, including our sales of NUZYRA, sales by our collaboration partners with respect to which we are entitled to royalties, our third-party manufacturers and supply chain, our research and development efforts, our clinical trials and our employees.

Until we can generate a sufficient amount of product and royalty revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through a combination of public or private equity offerings, debt or other structured financings, strategic collaborations, grant funding and government funding. We do not have any committed external sources of funds other than the rights under the BARDA contract and the rights to contingent milestone payments and/or royalties under the Almirall Collaboration Agreement, the Almirall China License, the Tetraphase License Agreement and the Zai Collaboration Agreement, which are terminable by Almirall, Tetraphase and Zai, respectively, upon prior written notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights. Future debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additionally, future equity or debt financing may be difficult to obtain on favorable terms, if at all, complicated by the increased volatility within the global financial markets as a result of the COVID-19 pandemic. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, NUZYRA, sarecycline, future revenue streams, research programs, product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market NUZYRA, sarecycline or our other product candidates that we may otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles of the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to, among other items, accounts receivable and related reserves, inventory and related reserves, goodwill, accrued sales allowances, net product revenue, government contract service revenue, government contract grant revenue, collaboration and royalty revenue, leases, stock-based compensation arrangements, amortization of the debt discount and issuance costs under the R-Bridge Loan Agreement, manufacturing and clinical accruals, useful lives for depreciation and amortization of long-lived assets and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Refer to Note 18, *Recent Accounting Pronouncements*, to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

During the nine months ended September 30, 2021 and the year ended December 31, 2020, we did not engage in any off-balance sheet financing activities, including the use of structured finance, special purpose entities or variable interest entities.

Contractual Obligations and Commitments

There have been no material changes in our contractual obligations and commitments as of September 30, 2021, as compared to those disclosed in *"Management's Discussion and Analysis of Financial Condition and Results of Operations— Contractual Obligations and Commitments"* in our 2020 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

Our cash and cash equivalents balance as of September 30, 2021 consisted solely of cash and cash equivalents. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, including interest rate changes resulting from the impact of the COVID-19 pandemic. However, a sudden change in market interest rates would not be expected to have a material impact on the fair market value of our cash and cash equivalents balance. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our cash and cash equivalents balance.

We engage CROs and contract manufacturers on a global scale. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. We currently do not hedge any such foreign currency exchange rate risk. Transactions denominated in currencies other than U.S. dollars are recorded based on exchange rates at the time such transactions arise and were less than 1.0% of total liabilities as of September 30, 2021.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 2021, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, as amended, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings

Information in response to this Item is incorporated herein by reference from Note 17, *Commitments and Contingencies*, to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

There have been no material changes from the risk factors set forth in our 2020 Form 10-K other than as set forth below.

If BARDA were to eliminate, reduce, or delay funding for our contract, we would experience a negative impact on our programs associated with such funding and perhaps on our ability to maintain the infrastructure necessary to maximize our NUZYRA commercial opportunity.

On December 18, 2019, we entered into a contract with BARDA to support the development of NUZYRA for the treatment of pulmonary anthrax and the fulfillment of FDA PMRs associated with NUZRYA's initial approval. The BARDA contract also includes the ability for BARDA to procure up to 10,000 treatment courses of NUZYRA for use against potential biothreats. The first procurement of NUZYRA was delivered to and accepted by BARDA in June 2021. The three additional procurements of NUZYRA under the BARDA agreement have not yet been activated and represent a maximum of approximately $115.3 million of funding under the contract. Activation is contingent upon our future progress in the ongoing anthrax development program and will be triggered upon achievement of the following development milestones: (1) BARDA's receipt of positive top line data from our pilot efficacy study for the treatment of inhalation anthrax in rabbits (CLIN 0006), (2) BARDA's receipt of positive top line data in PEP and treatment of inhalation anthrax from a combination of our pilot and pivotal efficacy studies in animal models (CLIN 0007) and (3) our receipt of sNDA approval from the FDA for treatment of inhalational anthrax (CLIN 0008). If BARDA were to eliminate, reduce, or materially delay funding, including with respect to further procurements under the BARDA contract due to our failure to achieve the developmental milestones on our anticipated timeline or otherwise, or prohibit reimbursement of some of our incurred costs, we would have to seek additional funding to continue development of NUZYRA for the treatment of anthrax or significantly decrease or cease the product's development for that indication. Moreover, a loss of BARDA funding could jeopardize our ability to maintain the infrastructure needed to maximize NUZYRA's commercial potential, and to fulfill NUZYRA's FDA PMRs in a timely manner.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	Form 8-K	001-36066	3.1	October 31, 2014
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation.	Form 8-K	001-36066	3.2	October 31, 2014
3.3	Certificate of Elimination of Series A Junior Participating Preferred Stock	Form 8-K	001-36066	3.1	July 24, 2015
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation.	Form 10-Q	001-36066	3.4	August 9, 2021
3.5	Amended and Restated Bylaws.	Form 8-K	001-36066	3.1	April 16, 2015
4.1	Specimen Common Stock Certificate.	Form S-3	333-201458	4.2	January 12, 2015
4.2	Form of Warrant Agreement issued to Hercules Technology II, L.P. and Hercules Technology III, L.P.	Form 8-K	001-36066	4.1	October 5, 2015
4.3	Form of Warrant Agreement issued to Hercules Technology II, L.P. and Hercules Technology III, L.P.	Form 8-K	001-36066	4.1	December 13, 2016
4.4	Warrant Agreement, dated as of June 27, 2017 issued to Hercules Capital, Inc.	Form 8-K	001-36066	4.1	June 29, 2017
4.5	Warrant Agreement, dated as of August 1, 2018 issued to Hercules Capital, Inc.	Form 10-Q	001-36066	4.5	August 2, 2018
4.6	Warrant Agreement, dated as of August 5, 2020 issued to Hercules Capital, Inc.	Form 10-Q	001-36066	4.9	August 10, 2020
10.1*^	Supply Agreement, dated July 14, 2021, between Paratek Pharmaceuticals, Inc. and CARBOGEN AMCIS AG.				
10.2*^	Modification of Contract No. 2, dated July 29, 2021, between Paratek Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services.				
10.3*^	Modification of Contract No. 3, dated September 23, 2021, between Paratek Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services.				
31.1*	Certification of the Company's Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of the Company's Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
32.1*	Certification of the Company's Chief 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 the Company's 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.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed or furnished herewith.

^ Certain confidential information contained in this exhibit has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 8th day of November 2021.

Paratek Pharmaceuticals, Inc.

By: /s/ Evan Loh M.D.

Evan Loh M.D.
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Sarah Higgins

Sarah Higgins
Vice President, Finance and Controller
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Execution Version

Supply Agreement

Between

Paratek Pharmaceuticals, Inc.

and

CARBOGEN AMCIS AG

Date

July 14, 2021

Table of Contents

THIS AGREEMENT ("**Agreement**"), dated July 14, 2021 (the "**Effective Date**"), is

BETWEEN:

Paratek Pharmaceuticals, Inc., a company having a place of business at 1000 First Avenue, Ste. 200, King of Prussia, PA 19406, USA ("**Customer**")

AND:

CARBOGEN AMCIS AG, a company having a place of business at Hauptstrasse 171, CH 4416 Bubendorf, Switzerland ("**Supplier**" and, collectively with Customer, the "**Parties**", and each, a "**Party**").

WHEREAS:

A. Customer is the owner of certain technology and patent rights regarding the Product (as defined herein) having the description set out in Exhibit A and Exhibit B;

B. Customer has received approval with the United States Food and Drug Administration and/or its foreign equivalents, an Investigational New Drug Application ("**IND**") and a New Drug Application ("**NDA**"), or the foreign equivalents thereof, for certain formulations containing the Product;

C. Supplier is engaged in the business of performing contracted process development, Manufacturing and supply services of active pharmaceutical ingredients ("**APIs**") and intermediates; and

D. Customer desires that Supplier Manufacture the Product in bulk quantities and Supplier desires to perform such services, each on the terms and conditions set out in this Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

Article 1 Interpretation

1.1. Definitions

In this Agreement, in addition to words and phrases defined where they are used, the following words and phrases shall have the following meanings:

(a) "**Affiliate**" of a Party shall mean any entity, directly or indirectly, controlling, controlled by, or under common control with a Party. For purposes of this definition, "**controlling**" (including, "**controlled by**" and "**under common control**") shall mean: (i) ownership of at least fifty percent (50%) of the equity capital or other ownership interest in or of an entity; (ii) the power to control or otherwise direct the affairs of an entity; (iii) in the case of non-stock organizations, the power to control the distribution of profits of an entity; or (iv) such other relationship as, in fact, results in actual control over the management, business, and affairs of an entity;

(b) "**Agreement**" means this Supply Agreement for the Product, including all Exhibits attached hereto, and as set forth in the recitals hereto;

(c) "[***]" shall have the meaning set forth in Section 3.9;

(d) "**API**" shall have the meaning set forth in the recitals hereto;

(e) "**Applicable Law**" means any applicable law, statute, rule, regulation, order, judgment or ordinance of any governmental or regulatory authority or agency;

(f) "**Applicable Regulatory Authority**" means FDA, EMEA or other equivalent governmental or regulatory authorities or agencies and any successors thereto;

(g) "**Backup Supplier**" shall have the meaning set forth in Section 3.12;

(h) "**Base Exchange Rate**" shall have the meaning set forth in Section 9.1(b);

(i) "**Batch**" means, with respect to a Product, a discrete output or isolation from a set of unit operations described in the then-current batch record instructions for such Product. The batch size for each Product shall be related to the capacity of a given equipment train and is dependent on the maximum utilization of the bottle-neck reactor and vessel. As of the Effective Date, the initial batch size for the Product will be approximately [***] (as specified in Exhibit C)]. The initial batch size may be adjusted from time to time upon mutual agreement of the Parties.

(j) "**Binding Forecast**" shall have the meaning set forth in Section 4.1;

(k) "**Business Day**" means any day on which banking institutions in Boston, Massachusetts and Bubendorf, Switzerland are open for business;

(l) "**Campaign**" means a schedule of one or more discrete batches of Product Manufactured in sequence by Supplier without pausing to change over to manufacture of any other product;

(m) "**cGMP Requirements**" means the current Good Manufacturing Practices standards required under ICH Q7A guideline or any similar standards of applicable governmental or regulatory authorities as defined in the Quality Agreement;

(n) "**Change of Control**" means any transaction or series of transactions wherein (i) the voting securities of Supplier outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such transaction or transactions; (ii) the stockholders or equity holders of Supplier approve a plan of complete liquidation of Supplier, or an agreement for the sale or disposition by Supplier of all or substantially all of Supplier's assets, other than to an Affiliate; (iii) a Third Party becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of Supplier; or (iv) substantially all of Supplier's business or assets which relate to this Agreement are sold or otherwise transferred to a Third Party;

(o) "**Chemical Synthesis**" means established and reliable execution of chemical reactions in order to produce the Product by applying chemical and physical manipulations usually involving one or more reactions;

(p) "**Confidential Information**" means all written information and data provided by the Parties to each other hereunder or under the Outsourcing Agreement and identified as being "**Confidential**" and provided to the recipient, except that the term "**Confidential Information**" shall not apply to any information or any portion thereof which:

(i) was known to the recipient or any of its Affiliates, as evidenced by its written records, before receipt thereof under this Agreement;

(ii) is disclosed to the recipient or any of its Affiliates, without obligations of confidentiality, during the Term by a Third Party who has the right to make such disclosure;

(iii) is or becomes part of the public domain through no breach of this Agreement by the recipient; or

(iv) the recipient can demonstrate through competent written records is independently developed by or for the recipient or any of its Affiliates by individuals or entities who have not had access to the information disclosed under this Agreement;

Confidential Information may include, without limitation, data, know-how, formulae, processes, designs, sketches, photographs, plans, drawings, specifications, samples, reports, studies, data, findings, inventions, ideas, production facilities, machines, production capacities, prices, market share, research and development projects, and other market data. For the purposes of this Agreement, Master Batch Record shall be deemed the Confidential Information of Customer and the Product Specifications shall be deemed the Confidential Information of Customer;

(q) "**Correspondence**" shall have the meaning set forth in Section 19.10;

(r) "**Customer**" shall have the meaning set forth in the recitals hereto;

(s) "**Customer Licensee**" means any Third Party to whom Customer grants a license or a right to research, develop, make, have made, use, sell, have sold, import, export or otherwise exploit a Product or Customer Product;

(t) "**Customer Material**" means the compound satisfying the Customer Material Specification;

(u) "**Customer Material Specifications**" means the specifications for the Customer Material set forth in the Quality Agreement, as such may be amended from time to time in accordance with its terms;

(v) "**Customer Product**" means any pharmaceutical product owned, controlled or sold by Customer, its Affiliates or Customer Licensees that incorporates or is derived from a Product;

(w) "**Customer Technology**" means:[***]

(x) "**Drug Master File**" means a submission to the Applicable Regulatory Authority that provides detailed information about facilities, processes or articles used in the Manufacture, processing, packaging and storing of a drug or excipient, among others, in order to obtain appropriate Applicable Regulatory Authority approval for the production for that drug;

(y) "**Effective Date**" shall have the meaning set forth in the recitals hereto;

(z) "**EMEA**" means the European Medicines Agency and any successors thereto;

(aa) "**Facilities**" or "**Facility**" shall have the meaning set forth in Section 3.1(a);

(bb) "**FDA**" means the United States Food and Drug Administration and any successors thereto;

(cc) "**FD&C Act**" means the Federal Food, Drug and Cosmetic Act, as the same may be amended or supplemented from time to time;

(dd) "**Fees**" means the fees specified in Exhibit C, as may be amended by the Parties in accordance with this Agreement;

(ee) "**Improvements**" means, in relation to any Intellectual Property, any and all versions, adaptations, modifications, improvements, enhancements, changes, revisions, translations and derivative works (whether complete or incomplete), of, to, in or based upon such Intellectual Property;

(ff) "**IND**" shall have the meaning set forth in the recitals hereto.

(gg) "**Indemnified Party**" shall have the meaning set forth in Section 14.3;

(hh) "**Indemnifier**" shall have the meaning set forth in Section 14.3;

(ii) "**Indemnitee**" shall have the meaning set forth in Section 14.4;

(jj) "**Initial Term**" shall have the meaning set forth in Section 2.1;

(kk) "**Intellectual Property**" means anything that is protected by any Rights in and to any and all patents, trade-marks, copyrights, industrial designs, Confidential Information, know-how and processes, and all other intellectual and industrial property Rights whatsoever and world-wide (whether registered or unregistered and including Rights in any application for any of the foregoing);

(ll) "**Inventions**" shall have the meaning set forth in Section 11.4;

(mm) "**Latent Defect**" shall have the meaning set forth in Section 8.1;

(nn) "**Manufacture**," "**Manufactured**" or "**Manufacturing**" means all activities involved in the production of the Product to be supplied to Customer or its Affiliates hereunder, including the preparation, formulation, finishing, testing, storage and packaging for shipment of Product and the handling, storage and disposal of any residues or wastes generated thereby;

(oo) "**Manufacturing Process**" means the activities set out in (i) this Agreement, (ii) the Master Batch Record and (iii) Supplier's standard operating procedures for the Manufacturing, characterization and testing, and bulk packaging and storage of the Product;

(pp) "**Master Batch Record**" means the complete detailed Manufacturing and control instructions and specifications for the Manufacturing Process for the Product, as defined by the applicable validation protocol and cGMP Requirements, as may be amended from time to time; in accordance with cGMP Requirements, or by mutual agreement of both Customer and Supplier;

(qq) "**Materials**" means any and all materials, reagents, chemicals, compounds, physical samples, models, specimens and any other similar physical substances that are used in the Manufacture of the Product except for Customer Materials, including processes and activities leading up to and peripheral to the Manufacture of the Product;

(rr) "**Maximum Production Capacity**" shall have the meaning set forth in Section 3.4;

(ss) [***] shall have the meaning set forth in Section 3.1(c);

(tt) "**NDA**" shall have the meaning set forth in the recitals hereto;

(uu) "**Notice of Rejection**" shall have the meaning set forth in Section 8.1;

(vv) "**Out Of Specification**" shall have the meaning set forth in Section 8.1;

(ww) "**Outsourcing Agreement**" means the Outsourcing Agreement by and between Customer and Supplier, dated as of December 30, 2016, as amended by the first amendment to the Outsourcing Agreement, dated as of December 18, 2018;

(xx) "**Parties**" or "**Party**" shall have the meaning set forth in the recitals hereto;

(yy) "**Product**" means the compound product as described in Exhibit A and Exhibit B satisfying the Product Specifications;

(zz) "**Product Specifications**" means the specifications for the Product set forth in the Quality Agreement, as such may be amended from time to time in accordance with its terms;

(aaa) "**Purchase Order**" shall have the meaning set forth in Section 6.1;

(bbb) "**Quality Agreement**" shall mean that certain Quality Technical Agreement Relating to Drug Substance Commercial Contract Manufacturing Services by and between Customer and Supplier, dated as of February 25, 2019 and as amended from time to time;

(ccc) "**Recall**" means any action by Supplier, Customer or any of their respective Affiliates, to recover possession of the Product or finished products

containing the Product shipped to Third Parties. "**Recalled**" and "**Recalling**" shall have comparable meanings;

(ddd) "**Renewal Term**" shall have the meaning set forth in Section 2.1;

(eee) "**Rights**" shall mean any and all proprietary, possessory, use and ownership rights, titles and interests (whether beneficial or legal) of all kinds whatsoever, howsoever arising, world-wide and whether partial or whole in nature;

(fff) "**Rolling Forecast**" shall have the meaning set forth in Section 4.1;

(ggg) "**Scope of Work**" shall have the meaning set forth in Section 6.6;

(hhh) "**Seizure**" means any action by an Applicable Regulatory Authority in any jurisdiction, to detain or destroy any Product or any intermediate or finished products containing the Product or prevent release of the Product or finished products containing the Product. "**Seized**" and "**Seizing**" shall have comparable meanings;

(iii) "**Services**" refers to any activities undertaken by Supplier relating to the Product, as referenced in Section 6.6;

(jjj) "**Steering Committee**" shall have the meaning set forth in Section 7.4;

(kkk) "**Supplier**" shall have the meaning set forth in the recitals hereto;

(lll) "**Supplier Employees**" shall have the meaning set forth in Section 12.5(a);

(mmm) "**Supplier Representatives**" shall have the meaning set forth in Section 14.1;

(nnn) "**Supplier Technology**" means, to the extent such is not Customer Technology:[***]

(ooo) "**Taxes**" shall have the meaning set forth in Section 9.3;

(ppp) "**Term**" means the Initial Term and the Renewal Term, if applicable;

(qqq) "**Territory**" means the United States of America and its territories and possessions and any other countries in the world added to the definition of "**Territory**" pursuant to Section 3.10;

(rrr) "**Third Party**" means any party other than a Party to this Agreement or an Affiliate of a Party to this Agreement;

(sss) "[***]" shall have the meaning set forth in Section 11.7;

(ttt) "[***]" shall have the meaning set forth in Section 11.7;

(uuu) "[***]" shall have the meaning set forth in Section 11.7;

(vvv) "[***]" shall have the meaning set forth in Section **Error! Reference source not found.**;

(www) "**Yield**" means, with respect to any Batch of Product Manufactured by Supplier under this Agreement, a percentage equal to the amount of Omadacycline Tosylate in kg contained in such Batch of Product delivered and accepted by Customer under this Agreement divided by the amount of Omadacycline crude (corrected by assay) used in the Manufacturing Process of such Batch of Product.

1.2. Other Definitions

Any words defined elsewhere in this Agreement shall have the particular meaning assigned to the words.

1.3. Currency

In this Agreement, all references to money or payments means Swiss francs (CHF) or U.S. dollars (USD), as applicable (see Section 9.1 for further details).

1.4. Headings

The headings in this Agreement are solely for convenience of reference and shall not be used for purposes of interpreting or construing the provisions hereof.

1.5. Exhibits

The Exhibits attached hereto shall be deemed to form an integral part of this Agreement. In the event of a conflict between the terms and conditions set out in this Agreement and the terms and conditions set out in any Exhibit hereto, the terms and conditions set out in this Agreement shall govern.

1.6. Applicable Law

This Agreement shall be governed by and construed in accordance with the substantive laws of the [***], excluding any rules of conflicts of laws that would apply the substantive laws of any other jurisdiction.

1.7. Appendix Terms

Notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree to comply with any covenants set forth in Appendix A. The Parties further acknowledge and agree that any representations and warranties set forth in Appendix A are true and correct as of the Effective Date of this Agreement. The provisions in Appendix A will control over the other provisions in this Agreement to the extent of any conflict.

Article 2 Term

2.1. Term

This Agreement shall commence on the Effective Date and shall continue for a period of [***] (the "**Initial Term**"), unless earlier terminated in accordance with the terms of this Agreement. Should either Party fail to notify the other at least [***] in advance of the termination date (either after the Initial Term or a Renewal Term) of their intention to terminate the Agreement, then the Agreement shall automatically renew for another [***] period (unless otherwise mutually agreed by the Parties or earlier terminated pursuant to Section 18.1) (each [***] renewal, a "**Renewal Term**"). For the avoidance of doubt, [***].

2.2. Effect of Expiration on Purchase Orders

For the avoidance of doubt, any signed Purchase Order which has not been completed at the date of expiry shall continue in effect unless cancelled in accordance with Section 6.4 or Article 18. For further avoidance of doubt, the terms and conditions of this Agreement shall remain applicable to any such signed Purchase Order which continues in effect.

Article 3 Supply of Product

3.1. Supply of Product

(a) During the Term, Supplier shall Manufacture the Product and perform all Services at its facilities located at Bubendorf, Switzerland, Aarau, Switzerland and at Hunzenschwil, Switzerland (such facilities, the "**Facilities**" and each, a "**Facility**"). Supplier shall supply to Customer or Customer's designee, the Product, Manufactured in accordance with the accepted Purchase Order placed by Customer, Master Batch Record, the Product Specifications, the Quality Agreement and cGMP Requirements and, subject to Section 3.1(b), in such quantities as ordered by Customer in Purchase Orders submitted pursuant to Section 6.1 and accepted pursuant to Section 6.2.

(b) The Product manufactured and delivered to Customer by Supplier under this Agreement may be [***].

(c) [***]

(d) The Parties shall, on an annual basis beginning on [***] of the Effective Date, during the Steering Committee meetings held pursuant to Section 7.4, [***].

(e) In the event the Product Manufactured and delivered to Customer under a Purchase Order is more than [***] or if Customer otherwise reasonably requests, [***].

(f) For clarity, nothing in this Section 3.1 limits Supplier's liability under this Agreement or under law, including liability for negligence, willful misconduct, or failure to comply with the Product Specifications.

3.2. Manufacturing Services

Supplier shall make available its labor, equipment and Facilities for use in Supplier's Manufacture and characterization of the Product, including in-process and quality control analyses, release testing, stability testing (pursuant to Section 5.4), storage and bulk packaging of the Product, and shipping of the Product, in accordance with the terms and conditions of this Agreement.

3.3. Supply of Materials and Customer Material

(a) Materials

(i) Supplier shall, at its cost, be responsible for the purchase, planning, supply, control, testing, release and compliance of all Materials (other than Customer Materials unless expressly otherwise set forth in this Agreement) required for the Manufacture of the Product and performance of Services under accepted Purchase Orders.

(ii) Supplier shall ensure that all Materials (other than Customer Material unless expressly otherwise set forth in this Agreement) used in the Manufacture of the Product and performance of Services shall comply with the specifications mutually agreed by the Parties in writing and applicable requirements of the Quality Agreement.

(iii) Supplier shall test and inspect all Materials as set forth in the Quality Agreement and Supplier's standard incoming inspection and testing procedures, which at a minimum shall include appearance and identity testing.

(b) Customer Material

(i) Customer or its designee (for which Customer is responsible) shall, at its cost, be responsible for the planning, supply, control, testing, release and compliance of all Customer Materials supplied to Supplier that are required for the Manufacture of the Product and performance of Services under accepted Purchase Orders. Customer shall ensure that all Customer Materials meet the Customer Material Specifications.

(ii) Customer or its designee (for which Customer is responsible) shall, at its cost, be responsible for the qualification of suppliers of Customer Materials.

(iii) Customer or its designee (for which Customer is responsible) shall ensure that all Customer Materials used in the Manufacture of the Product and performance of Services shall meet applicable requirements set forth in the Quality Agreement.

(iv) Supplier shall test and inspect all Customer Materials in accordance with the Quality Agreement and Supplier's standard incoming inspection and testing procedures. Supplier shall also independently release Customer Materials (but Supplier shall not use any Customer Materials that have not also been released by Customer).

(v) Upon receipt of a Purchase Order from Customer, Supplier shall inform Customer of the latest delivery date required for Customer Materials [***]. Customer shall use commercially reasonable efforts to coordinate delivery of Customer Materials by that date according to [***]).

(vi) If Customer is unable to deliver Customer Materials by the date required by Supplier, this shall be promptly communicated to Supplier. Supplier shall use commercially reasonable efforts to reallocate capacity and accommodate the planned Campaign at a later date. [***]. Supplier shall be released from its obligation under the relevant Purchase Order and any associated penalties regarding delivery date for the corresponding Product. In the event of any such delay in the delivery of Customer Materials to Supplier, the Parties shall negotiate in good faith and agree upon a revised schedule for the supply of Product to Customer or its designee, which revised schedule shall be binding on Supplier in accordance with this Agreement.

(vii) In the event that Customer Materials delivered to Supplier are found by Supplier to be non-conforming to the Customer Material Specifications at the time of delivery of such Customer Materials to Supplier and Customer challenges this finding, the Parties shall conduct a joint investigation. If Supplier and Customer are unable to resolve the issue of non-compliance then a sample of the relevant Customer Material shall be submitted to an independent laboratory reasonably acceptable to both Parties for testing against the Customer Material Specifications, and determination whether or not the Customer Material did not comply with the Customer Material Specifications at the time of delivery to Supplier. The test results of the independent laboratory testing shall be final and binding upon Customer and Supplier, [***]. In such event, except as set forth in Section 3.3(b)(vi), Supplier shall be released from its obligation with respect to the relevant Purchase Order and any associated penalties regarding a delayed delivery date for the corresponding Product under such Purchase Order. In the event that Customer delivers any such non-conforming Customer Materials, the Parties shall negotiate in good faith and agree upon a revised schedule for the supply of the Product to Customer or its designee, which revised schedule shall be binding on Supplier in accordance with this Agreement.

(viii) Customer shall provide Supplier with a Certificate of Analysis, a BSE/TSE statement and a Certificate of Compliance, data on the chemical and physical properties, toxicity, and handling, storing, and shipping information for any Customer Materials (MSDS or equivalent) and any other information that is necessary for the safe handling and transportation of Customer Materials. Customer shall update all of such information provided to Supplier after such updated information becomes available or known to Customer.

(ix) Customer shall hold title to any Customer Materials used in the Manufacture of the Product and performance of Services hereunder by Supplier. For the avoidance of doubt, title to the Product shall remain with Supplier until delivery of the Product to the carrier as set forth in Section 7.2(d).

Following receipt of Customer Materials from Customer and until the delivery of Product containing such Customer Materials, Supplier shall bear the risk of any loss of or damage to such Customer Materials resulting from [***]. Supplier shall retain exclusive control over Customer Materials and shall not transfer any portion of them to any Third Party without the prior written consent of Customer. Supplier shall identify Customer Materials at all times as Customer property and shall segregate same from other substances except as needed for the Manufacture of the Product and performance of the Services. Supplier shall not take any action inconsistent with Customer's ownership interest in Customer Materials, including but not limited to, Supplier shall keep Customer Materials free and clear of any liens, encumbrances, or security interests resulting from the actions or omissions of Supplier or its Affiliates and, in the event of any such liens, encumbrances, or security interests, Supplier shall promptly remove the same at its sole expense.

3.4. Production Capacity

Supplier agrees to provide to Customer all such facility and Manufacturing capacity to perform the Manufacturing Process as required to meet the Product requirements as described in the

then-current Rolling Forecast (as defined below). Supplier agrees that it shall provide to Customer at least [***] prior written notice of any scheduled shutdown at any Facility that may impact Supplier's ability to Manufacture and timely deliver the Product to Customer under this Agreement, [***].

As of the Effective Date, Supplier agrees to make available to Customer a production capacity of [***] (the **"Maximum Production Capacity"**), unless the Parties otherwise mutually agree to increase such Maximum Production Capacity. The Maximum Production Capacity will be produced in [***] in accordance with the Rolling Forecasts (as defined below). The minimum Campaign size will be [***]. The Parties may mutually agree in accordance with the Rolling Forecast process set forth in Section 4.1 to increase the number of OMC Tosylate or OMC Base Batches in a given campaign in the event additional capacity is available. In this case, the Parties shall discuss a potential revised cost per kilogram commensurate with the agreed upon campaign size, if applicable.

For the avoidance of doubt, Customer shall [***] but shall not be required to purchase an amount of Product equal to the Maximum Production Capacity in any calendar year during the Term of this Agreement.

3.5. Processing Changes

(a) Supplier shall not make any material changes to the Manufacturing Process, starting materials, the Master Batch Record or Product Specifications for the Manufacture of the Product except in accordance with the Quality Agreement. For clarity, formatting changes in the documentation related to the Master Batch Record shall not be deemed a "**material**" change under this Section 3.5(a).

(b) Customer (or Supplier, if changes are necessitated by Applicable Law) may request reasonable changes to the Manufacturing Process, the Master Batch Record, the Product Specifications, storage, testing or analytical methods or any starting materials for the Manufacture of the Product[***]. The notice of any such change by Customer shall comply with the cGMP documentation system and standard operating procedures maintained by Supplier at the Facilities. No material modifications or additions to the machinery, equipment and other fixed assets used by Supplier in the Manufacture and supply of the Product to Customer shall be required without the consent of Supplier, which consent may be granted or withheld in Supplier's sole discretion.

(c) In the event of a change to the Manufacturing Process, the Master Batch Record or the Product Specifications, the relevant documents and related Exhibits to this Agreement shall be revised accordingly.

(d) All operational Master Batch Records and standard operating procedures utilized by Supplier are in the German language. Any requirement by Customer for translation of such records shall be billed at cost.

3.6. Monitoring of Facilities

Customer shall have the right to have a representative present at each Facility to observe the performance of the Manufacturing Process by Supplier during normal business hours with at least [***] advance notice. Supplier shall have the right to reasonably restrict such observation access to prevent undue interference with Supplier's business operations or compromise Supplier's confidentiality obligations to Third Parties; provided, however,

Customer's observation access shall be absolute with regard to the Manufacturing Process for the Product. As such it is Supplier's obligation to segregate Third Party documents and materials from Customer's documents and materials and Customer shall not be restricted from observing any part of Customer's Manufacturing Process and related documentation.

One performance observation of the Manufacturing Process every [***] shall be free of charge.

3.7. Subcontracting

Supplier shall obtain Customer's prior written approval, in accordance with the Quality Agreement, to use a subcontractor to perform services under this Agreement, such approval not to be unreasonably withheld, conditioned or delayed. Any and all such contractors shall perform such services in accordance with the terms and conditions of this Agreement, and Supplier shall remain liable for the performance of its obligations under this Agreement. Supplier may use the Third Party suppliers set forth in Schedule 4 of the Quality Agreement for such specific activities set forth opposite their respective name(s) in such Schedule. It is hereby agreed that Customer may authorize the use of additional Third Party suppliers under this Agreement in accordance with the Quality Agreement. Supplier agrees to use the Third Party suppliers identified, as applicable, in Schedule 4 of the Quality Agreement as the exclusive suppliers of starting materials for the Product Manufacturing Process and any deviation from said supply sources requires the prior written approval of Customer, in accordance with the Quality Agreement, such approval not to be unreasonably withheld, conditioned or delayed.

3.8. [***]

3.9. [***]

3.10. Territory Expansion

At any time during the Term, Customer may provide written notice to Supplier of its intent to expand the Territory under this Agreement to include one or more additional countries or territories. Promptly following such notification, the Steering Committee shall meet to discuss any expansion of Supplier's Manufacturing capabilities necessitated by such expansion in accordance with clause (b) of Section 7.4 and the Parties shall execute an amendment that (a) amends the definition of "**Territory**" under Section 1.1(qqq) to include such additional countries or territories and (b) modifies the provisions of this Agreement as necessary in order to reflect the regulatory requirements of such additional countries or territories. For clarity, neither Party shall be obligated to amend the definition of Territory at any point during the Term.

3.11. Supply to Customer Licensees

In the event Customer delivers a written request to Supplier requesting that Supplier engage in negotiations with a Customer Licensee on the terms of a definitive agreement pursuant to which Supplier would Manufacture and supply Product to such Customer Licensee or a designee of a Customer Licensee, Supplier shall use commercially reasonable good faith efforts to negotiate and execute such agreement on substantially the same terms of this Agreement (including pricing, orders, forecasting, delivery, non-conformance, failure to supply, term and termination).

3.12. Alternative Supply

At any time during the Term, Customer may elect to qualify one (1) or more alternative Manufacturing facilities (whether owned by a Third Party, Customer or by one of Customer's Affiliates) to Manufacture the Product (each, a "**Backup Supplier**"). Customer shall be responsible for any costs associated with qualifying Backup Suppliers. Supplier shall use commercially reasonable efforts to cooperate with the qualification of any Backup Supplier, including (a) technology transfer of all Supplier Technology necessary or useful for the Manufacture of the Product; provided that, to the extent that such technology and know-how constitutes Confidential Information of Supplier, it shall be subject to the provisions of Article 12 and Customer's designated alternative supplier shall be required to enter into a confidentiality agreement with Supplier containing substantially the same terms as Article 12 and (b) providing Customer and any Backup Supplier with consulting services related to the Manufacture, quality control and quality assurance of the Product. Any work related to technology transfer or qualification of a second supplier shall be considered as Services under this Agreement as described in Section 6.6 For the avoidance of doubt, Supplier shall first prepare a customary Scope of Work describing the Services to be performed and the costs to Customer for the approval of Customer. No Services shall be commenced by Supplier unless (i) a customary Scope of Work relating to such Services has been agreed, executed and delivered by both Supplier and Customer; and (ii) a Purchase Order has been issued by Customer and accepted by Supplier relating to such Services, which Purchase Order references the specific Scope of Work and this Agreement. In case of disagreement on any Scope of Work, the Parties shall enter into good faith negotiations to reach a mutually satisfactory resolution with respect to such Scope of Work.

Article 4 Forecasts

4.1. Rolling Forecasts

Commencing within [***] from the Effective Date, Customer shall provide to Supplier on a calendar quarterly basis on or before the last Business Day of each calendar quarter during the Term, a rolling forecast for a [***] to [***] period commencing on the first day of the following calendar month (each, a "**Rolling Forecast**"). Supplier will review and respond to each Rolling Forecast within [***] of receipt. If Supplier does not accept a Rolling Forecast within such [***], then the Parties will discuss and agree upon a new Rolling Forecast. Each Rolling Forecast shall set out Customer's reasonable and genuine estimate of the quantities of the Product to be ordered by Customer and to be delivered by Supplier under this Agreement for the following [***] to [***]. The first [***] of each Rolling Forecast shall be binding firm purchase orders by Customer (each, a "**Binding Forecast**") and the remainder of each Rolling Forecast shall be non-binding, good faith estimates.

4.2. Supplier Commitment

Supplier shall use the mutually agreed [***] to [***] forecasts that Customer provides on a rolling basis to plan Campaigns during the applicable Rolling Forecast period. Any requested increase in supply of the Product in excess of the Maximum Production Capacity of Supplier is subject to mutual agreement of the Parties. The Parties acknowledge and agree that any placeholders for Supplier to reserve capacity for the Manufacture and supply of the Product for Customer shall be set forth in the Rolling Forecasts, which shall be prepared based on Customer's assessment of its supply needs at the time and consistent with the Maximum Production Capacity of Supplier, and Supplier shall reserve such requested capacity for Customer. Customer may request to reschedule the timing of production from time to time in accordance with the Binding Forecast and Supplier shall use its commercially reasonable efforts to comply with the delivery schedule.

For the avoidance of doubt, any request to reschedule the timing of a production within the Binding Forecast will be considered a cancellation and subject to the terms of Section **Error! Reference source not found.**.

Article 5 Testing and Samples

5.1. Release Testing

(a) Supplier shall perform release testing of all Batches of Product prior to delivery to Customer in accordance with the Quality Agreement, Product Specifications and the Master Batch Record, to determine whether such Batches of Product meet the requirements set out in the Product Specifications. Customer shall be responsible for the final release of Product prior to shipping and further processing.

(b) Supplier shall ensure that:

(i) its quality assurance department approves each Batch of Product for release promptly following successful completion of release testing done by its quality control department (in this Section 5.1(b)(i) "**promptly**" means [***]); and

(ii) release of any Batch of Product does not occur without the prior written approval of Customer in accordance with the Quality Agreement. Customer shall not unreasonably withhold or delay such approval.

(c) Supplier shall prepare a Certificate of Analysis and Certificate of Conformance (in forms set out in Exhibit D), setting out the results of the release testing and which shall be included with each Batch of Product shipped to Customer.

(d) Customer shall have the right to oversee the activities set forth in this Section 5.1 in accordance with the Quality Agreement.

5.2. Additional Release Testing

Customer reserves the right to conduct, in its sole discretion and at its expense, additional analytical testing on the Product.

5.3. Retention Samples

Supplier shall retain and store in accordance with cGMP Requirements, Applicable Law and Supplier's internal quality standard operating procedures, retention samples of each Batch of Product Manufactured under this Agreement as set forth in the Quality Agreement.

5.4. Stability Testing

If requested by Customer, Supplier shall be responsible for performing annual stability testing of the Product and shall ensure that all such testing is performed in compliance with the applicable ICH regulations (e.g. follow-up stability studies of commercially used products). Costs associated with annual stability testing shall be quoted separately from commercial unit pricing under a separate Scope of Work or Purchase Order (subject to Section 6.6), as applicable.

5.5. Reference Standards

If requested by Customer, Supplier shall be responsible for qualification and requalification of new reference standards. Costs associated with qualification and requalification of reference standards shall be quoted separately from commercial unit pricing under a separate Scope of Work or Purchase Order (subject to Section 6.6), as applicable.

Article 6 Purchase Orders

6.1. Placement of Purchase Orders

Consistent with the [***] the Maximum Production Capacity and minimum Campaign size as set forth in Section 3.4, and the Binding Forecast as set forth in Section 4.1, Customer shall place purchase orders with Supplier, stating Customer's required delivery data, anticipated delivery schedule and the anticipated Fees, in accordance with the Fee Schedule set out in Exhibit C, for each delivery of Product to be made under this Agreement (each, a "**Purchase Order**"). Purchase Orders must have at least [***] of lead time before anticipated delivery to allow sufficient time for Supplier's planning, raw material purchases, production and release. Each Purchase Order shall constitute a firm, binding order, upon Supplier's acceptance thereof in accordance with Section 6.2.

6.2. Acceptance of Orders

Supplier will acknowledge receipt of each Purchase Order and confirm the delivery date within [***] and shall use commercially best efforts to align with Customer's expected delivery date. Supplier may reject any Purchase Order placed by Customer that is not placed in accordance with this Agreement by giving written notice (e-mail shall constitute written notice) to Customer within a reasonable time, not to exceed [***] after receipt of each Purchase Order, setting out the reason for such rejection. In the event Supplier does not respond within [***], such Purchase Order shall be considered accepted by Supplier. In the event the terms and conditions of this Agreement conflict with the terms and conditions of the Purchase Order, the terms and conditions of this Agreement shall take precedence unless otherwise agreed upon by the Parties.

6.3. Delays

If, after acceptance of a Purchase Order, Supplier is unable for any reason to supply quantities of the Product in accordance with the Purchase Order placed by Customer under Section 6.1 on the timelines set forth therein, Supplier shall inform Customer within [***] of becoming aware of its inability to supply the Product of the expected duration of such inability and shall keep Customer informed on a timely basis of developments during any such period of time. The Parties shall cooperate to expedite the scheduling of the resumption of Manufacture of the Product by Supplier when any such inability has been alleviated. In the event of any delay in delivery of Product from the delivery date on the applicable Purchase Order for such Product, if such delay is: [***].

6.4. Cancellation of Purchase Orders

In the event that Customer cancels all or part of a Purchase Order already accepted by Supplier, Supplier shall use best efforts to reallocate capacity and mitigate any resultant costs of such cancellation. Except as expressly set forth in Sections 3.4, 6.3 and 6.5 and 18.2(d), the following shall be charged to Customer:[***]

6.5. Material Failure of Supply

If Supplier, for any reason, fails to supply at least [***] of Product ordered by Customer pursuant to valid Purchase Orders, in two successive campaigns, except as a result of a failure by Customer to provide Customer Materials (a) on the timeline required by this Agreement or (b) in accordance with the Customer Material Specifications during any period of [***] or longer beginning on the requested delivery date, in addition to and without limiting any other remedies available to Customer under Sections 3.12, 6.3 and 18.1, [***].

6.6. Services

From time-to-time during the Term, Customer may request that Supplier perform Services for Customer relating to the Product, including Services not directly performed in the Manufacture and supply of Product, for which Customer shall pay reasonable compensation to Supplier. The Parties shall negotiate reasonable costs for such Services. The Parties may mutually agree to adjust the Services or costs under any Scope of Work. Unless consented by Customer in advance in writing (with email being sufficient), which consent shall not be unreasonably withheld, Customer shall not be responsible for reimbursement of adjusted costs for Services under a Scope of Work. In the event that Supplier is willing to perform any such Services requested by Customer, Supplier shall first prepare a scope of work describing the Services to be performed and the costs to Customer for the approval of Customer (each a "**Scope of Work**"). No Services shall be commenced by Supplier unless (a) a Scope of Work relating to such Services has been agreed, executed and delivered by both Supplier and Customer; and (b) a Purchase Order has been issued by Customer and accepted by Supplier relating to such Services which Purchase Order references the specific Scope of Work and this Agreement.

Customer shall have the right to terminate any Scope of Work and corresponding Purchase Order for Services at any time on reasonable advance written notice to Supplier (without terminating this Agreement), in which case Customer shall be responsible for:[***]

Article 7 Shipment of Product

7.1. Storage of Product

Supplier shall ensure that all Product held in storage is stored in accordance with the Product Specifications until shipped to Customer under this Agreement and that all storage areas meet cGMP Requirements. [***]

Should any Product, during storage, change chemical composition, then Supplier and Customer shall agree upon a plan for disposition of the Product, including possible disposal, re-processing, reworking or using the Product "**as is**." For clarity, Supplier shall not commence any action set forth in the preceding sentence until such a plan has been agreed by Customer. The cost of re-processing or reworking the Product shall be borne by [***].

The cost of storage, monitoring (including any on-going analytical analysis), and insurance before shipment shall be borne by [***].

7.2. Release and Shipment of Product

(a) Supplier shall notify Customer by electronic transmission of each Batch of Product Manufactured by it under this Agreement in accordance with this Article 7 as soon as reasonably possible, and no later than [***], after Supplier's quality assurance department approves the Batch for release following successful completion

of the release testing procedures and Customer approves such Batch for release, pursuant to Section 5.1(b)(ii).

(b) Supplier shall pack and label shipping boxes and ship all orders of Product in a prompt and timely manner and in accordance with international transport guidelines and regulations, the Product Specifications, and Customer's reasonable written instructions including, as applicable, for such shipment and the terms of this Agreement.

(c) Supplier shall not sell or otherwise dispose of any Product except in accordance with the terms and conditions of this Agreement.

(d) The Product shall be shipped [***]. All freight, applicable taxes (excluding any and all income taxes, employment taxes and the like incurred by Supplier), duties, express and delivery charges shall be for Customer's account and shall not be subject to discount. Upon [***], delivery shall be deemed completed at which time risk of loss or damage and title to the Product shall pass to Customer.

7.3. Documentation

Supplier shall include with each shipment of Product shipped to Customer under Section 7.2:

(a) commercially appropriate documentation;

(b) a Certificate of Analysis and Certificate of Compliance in English for each Batch of Product included in the shipment, in the forms set out in Exhibit D; and

(c) a copy of any deviation or investigation reports concerning each Batch of Product shipped (to be sent separately from shipment as part of the Batch record documentation).

7.4. Steering Committee

The Parties agree to form a steering committee (the "**Steering Committee**") to oversee their interactions under this Agreement as provided herein. Each Party shall name a mutually agreed upon equal number of representatives to the Steering Committee, which shall meet either in person or remotely (as mutually agreed) at least [***], or as otherwise mutually agreed by the Parties. The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. The Steering Committee shall in particular have responsibility for the following: (a) reviewing key metrics for the Product's production and quality, and reviewing and monitoring any required remediation with respect to production and quality for the Product; (b) reviewing Supplier's capacity and short-term and long-term planning for clinical and commercial supply of the Product, including anticipating any capacity shortfalls and discussing the cost allocation of investments required to increase capacity or improve efficiencies; (c) [***]; (d) reviewing and discussing draft Scopes of Work; (e) reviewing and determining whether to approve price adjustments, if any, in accordance with Section 9.2; (f) [***]; and (g) establishing resource priorities and resolving resource conflicts.

Article 8 Acceptance of Shipments

8.1. Acceptance of Shipments

Customer or its designees shall, within a period of [***] following the date of physical receipt of any shipment of Product from Supplier, inspect the Product for any shortages or any defects or deviations of the Product Specifications ("**Out Of Specification**") that would be apparent from visual inspections and analysis of the Product. In the event that Customer is of the opinion that the Product is Out Of Specification at the time of delivery, Customer shall, within [***] after the date of physical receipt of Product, provide Supplier with a written notice to reject the Product (a "**Notice of Rejection**"), which shall include a description of the grounds for rejection and copies of test reports and testing methodology conducted on the Product, if any. However, with respect to any Out Of Specification Product which would not be apparent from a reasonable visual inspection and analysis on delivery, including in the case of any hidden defects, (a "**Latent Defect**") such Notice of Rejection shall be provided to Supplier promptly after discovery of such Latent Defect.

The failure of Customer or its designees to notify Supplier of any Out Of Specification Product in the manner set forth herein above shall constitute confirmation of the acceptance thereof.

8.2. Dispute of Rejected Product

Supplier may, at its option, within [***] of receipt of any Notice of Rejection under Section 8.1, challenge the Notice of Rejection by delivering written notice thereof to Customer. In the event that Supplier challenges the Notice of Rejection, Customer and Supplier shall conduct a joint investigation. If Supplier and Customer are unable to resolve the issue of non-compliance then a sample of the Product shall be submitted to an independent laboratory reasonably acceptable to both Parties for testing against the Product Specifications, and determination whether or not the non-compliance may be caused by a fault on the part of Supplier. The test results of the independent laboratory testing shall be final and binding upon Customer and Supplier, and the fees and expense of such laboratory testing shall be borne entirely by the Party against whom such laboratory's findings are made.

8.3. Remedies

(a) In the event Supplier fails to supply at least [***] of the units of Product ordered by Customer pursuant to a valid Purchase Order, at Customer's option, Customer's [***] remedy, except as otherwise set forth in this Agreement including in Sections 6.3 and 6.5, shall be for:[***]

(b) In the event that Customer issues a timely Notice of Rejection with respect to any Out Of Specification Product:[***]

The Party in possession of any rejected Product which does not comply with the Product Specifications or cGMP Requirements shall destroy, in accordance with all Applicable Law and in a manner to which Customer has given its prior written approval, all rejected Product in its possession, but only after the Parties have followed the procedures specified under Sections 8.2 and 8.3. No rejected Product shall be sold, reprocessed, salvaged, reclaimed or otherwise reused in any manner by Supplier or Customer without the prior written agreement of the Parties with the exception of use testing and analysis by Supplier or Customer in the investigating the cause of Product rejection. Representatives of the Party not performing the destruction shall be permitted to witness the destruction of the rejected Product under this Section 8.3.

Article 9 Costs and Fees

9.1. Fees

(a) Customer shall pay to Supplier, in respect of each Purchase Order placed by Customer, the applicable Fees as set forth in Exhibit C attached hereto for the Manufacture and supply of the Product in bulk quantities under this Agreement, in accordance with the terms of this Agreement.

(b) The pricing terms of the Agreement are subject to a foreign exchange rate price adjustment from the exchange between U.S. dollars and Swiss francs as reflected in the average of such exchange rate determined as of the time of the Effective Date (the "**Base Exchange Rate**"). In the event of any currency fluctuation of plus or minus [***] from the Base Exchange Rate between U.S. dollars and Swiss francs during each calendar year of the Term, then Supplier shall adjust the pricing terms for the Product based upon such currency fluctuation and such adjustment shall be based on a rate at the time of invoicing.

(c) Except as otherwise expressly provided in this Agreement, the Fees specified in each Purchase Order accepted by Supplier shall be full compensation for all Manufacturing and characterization activities and Materials in respect thereof. Customer shall make all requests for processing changes to be performed under this Agreement in writing under Section 3.5 and Supplier shall provide Customer a cost estimate for such work.

9.2. Adjustments to Fees

During the Term of this Agreement, either Party may request an increase or decrease of the Fees specified in Exhibit C no more than [***]; provided that such change in Fees shall be negotiated no later than [***] in which the request was made and shall take effect on [***] for which such Fee change is requested. For the avoidance of doubt, any request to increase or decrease of Fees made in [***] shall not take effect until [***] following the requested Fee change. Such change in Fees may be requested due to any of the following events:

(a) [***];

(b) any other cost adjustments mutually agreed to by the Parties via the Steering Committee.

Supplier shall make available to Customer records that substantiate any adjustment to Fees for a Product proposed by Supplier and Supplier shall provide Customer with any Customer records that provide evidence for an increase or decrease in Fees pursuant to subsection (a) of Section 9.2; such records to be considered Supplier's Confidential Information hereunder.

For the avoidance of doubt, the Party proposing an adjustment in the Fees shall notify the other Party of the adjustment by delivering to the other Party at least [***] prior to the effective date of the Fees adjustment, written notice of the proposed adjustment. Said written notice shall specify the effective date as [***] in which the Fee adjustment becomes effective and the amounts for the adjusted Fees. On receipt of such request, the Parties shall seek in good faith to agree to an adjustment of the Fees via the Steering Committee, based on such reasonable and objective evidence. Each Party shall use its commercially reasonable efforts to mitigate any cost increase. The Fees for any Product ordered by Customer prior to the effective date of the Fees adjustment shall be the Fees existing on the date Customer placed the Purchase Order, as set out in the Purchase Order.

9.3. Taxes

The Fees shall be exclusive of any taxes, customs duties, levies and other charges applicable to the supply of the Product under this Agreement ("**Taxes**"). Customer shall pay any Taxes and reimburse Supplier for any Taxes for which Customer is responsible but which have been paid by Supplier. Subject to compliance with laws, the Parties shall reasonably cooperate to eliminate or minimize the amount of any such Taxes imposed on the transactions contemplated in this Agreement. For clarity, Customer shall not be liable for any taxes incurred by the Supplier including, without limitation, income taxes, employment taxes, use taxes, and the like incurred by Supplier, or for any penalties or interest related to the failure of Supplier to collect sales, use, VAT or similar taxes.

Article 10 Invoicing and Payment

10.1. Issuance of Invoices

Supplier shall, in accordance with Section 10.2, invoice Customer for each Purchase Order accepted under Section 6.2 as follows:

10.2. Invoice Contents

All invoices issued by Supplier under Section 10.1 shall show:

(a) the actual quantity of Product shipped;

(b) the lot number of each Batch of Product shipped;

(c) the Fees for the quantity of Product shipped, based on the Fees for the Product set out in the applicable Purchase Order; and

(d) the Purchase Order number placed by Customer for the Product shipped.

If a Purchase Order is in US Dollars (USD), then the applicable invoice will be made in US Dollars (USD) based upon pricing in Swiss franc (CHF). If a Purchase Order is in Swiss franc (CHF), then the applicable invoice will be made in Swiss franc (CHF). If Customer disputes for any reason with the amount of any invoice submitted by Supplier, Customer shall notify Supplier of such dispute within [***] after the date of the invoice, and the Parties shall promptly attempt to resolve the dispute. If Customer does not notify Supplier of any such dispute within such [***] period, such invoice shall be final and binding on Customer and Supplier, subject to the correction of mathematical errors.

10.3. Delay of Shipment

If Customer delays shipment of Product released by Supplier in accordance with Section 7.2, Supplier may issue its invoice under Section 10.1 on or after the release, with reference to the Product released under Section 10.2.

10.4. Payment of Invoices

Each invoice provided by Supplier to Customer under Section 10.1, to the extent accurate, shall be paid by Customer to Supplier within [***] after the date of the invoice to the extent that Customer does not reasonably dispute that portion of the invoice in good faith.

All payments shall be made in U.S. dollars by SWIFT bank transfer directly to the Supplier account as specified in the respective Purchase Orders.

Article 11 Intellectual Property

11.1. Title

(a) The Parties agree that, as between Customer and Supplier, each Party owns its respective Confidential Information, Customer owns all Rights in and to the Customer Technology, the Product(s) and its Chemical Synthesis and Supplier owns all Rights in and to Supplier Technology.

(b) Supplier shall not knowingly use in the Manufacturing Process any Intellectual Property protected by any patent or patent application licensed to Supplier by any Third Party, except with the prior written consent of Customer.

11.2. No Grant of Rights

Except as otherwise provided herein, neither Party hereto shall be deemed by this Agreement to have been granted any Rights of the other Party.

11.3. Grant of License by Customer

During the Term, Customer hereby grants to Supplier a paid-up, royalty-free, non-exclusive license, without the right to sublicense, to Customer's Confidential Information and the Customer Technology reasonably necessary to Manufacture and supply to Customer the Product hereunder, but only for such purposes. The Parties agree that the license grant contained in this Section 11.3 is personal to Supplier only and shall be exercised by Supplier only, and Supplier agrees to make use of Customer's Confidential Information and the Customer Technology only in accordance with this license and not to disclose any such Confidential Information or Customer Technology to any Third Party, except that nothing herein shall prevent Supplier from disclosing to its permitted subcontractors under confidentiality obligations at least as strict as those that bind Supplier under this Agreement, as necessary to perform Supplier's obligations hereunder.

11.4. Ownership of Inventions

With respect to any ideas, innovations, Improvements or inventions (whether patentable or non-patentable) developed by Supplier during the Term of this Agreement and [***], the Parties agree that, as between Customer and Supplier, Customer shall own all Rights to such Inventions and may obtain patent, copyright, and other proprietary protection respecting such Inventions. Supplier agrees to promptly disclose any Inventions to Customer. Supplier agrees to assign (and cause its employees or permitted subcontractors to assign), and does hereby assign, any and all rights, title and interests of Supplier in, to or under any Inventions to Customer. [***]

11.5. Patents to Inventions

With respect to all Intellectual Property created or developed under this Agreement, [***].

11.6. No Use of Trademarks

Nothing contained herein shall give either Party any right to use any trademark of the other Party. All trademarks and service marks adopted by Customer to identify the Product or a Customer Product are and shall remain the property of Customer.

11.7. [***]

Article 12 Confidentiality & Publicity

12.1. Obligation of Confidentiality

It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose Confidential Information to the other. Each Party agrees:

(a) to keep and use in strict confidence all Confidential Information of the other Party that each Party acquires, sees, or is informed of, as a direct or indirect consequence of this Agreement and to not, without the prior written consent of the other Party, disclose any such Confidential Information or recollections thereof to any person or entity other than its corporate counsel, employees and contractors who are under an obligation of confidentiality on terms substantially similar to those set out in this Agreement, who have been informed of the confidential nature of the Confidential Information and who reasonably require such information in the performance of their duties under this Agreement;

(b) not to use, copy, duplicate, reproduce, translate or adapt, either directly or indirectly, any of the Confidential Information of the other Party or any recollections thereof for any purpose other than the performance of the Services and the Manufacture and characterization of the Product under this Agreement, without the other Party's prior written approval;

(c) that all copies, duplicates, reproductions, translations or adaptations of any Confidential Information of the other Party permitted to be made hereunder shall be clearly labelled as Confidential; and

(d) to take all reasonable steps to prevent material in its possession that contains or refers to Confidential Information of the other Party from being discovered, used or copied by Third Parties and to use reasonable steps to protect and safeguard all Confidential Information of the other Party in its possession from all loss, theft or destruction.

Upon the termination of this Agreement, each Party shall promptly destroy or return all Confidential Information to the disclosing Party in accordance with Section 18.4.

12.2. Disclosure with Consent

A Party receiving Confidential Information may, with the written consent of the disclosing Party, disclose such Confidential Information to entities or persons other than its corporate counsel, employees and contractors, on such terms and conditions as the disclosing Party may specify.

12.3. Publicity

During the Term, the Parties agree that no press release, public announcement or publication regarding this Agreement or the relationship of the Parties (except to the extent that it may be legally required), shall be made unless mutually agreed to in writing prior to the release or dissemination of any such press release, public announcement or publication.

12.4. Disclosure Required by Law

No provision of this Agreement shall be construed so as to preclude such disclosure of Confidential Information of the other Party as may be inherent in or reasonably necessary to the securing from any governmental agency of any necessary regulatory approval or license. To the extent required by legal process, subpoena, warrant, or court order, either Party may disclose Confidential Information only to the extent required to comply with said legal proceeding, provided that the Party obligated to make such disclosure shall, when lawfully permissible, provide reasonable prior notice the other Party so as to allow the other Party to take steps to oppose or limit the required disclosure.

12.5. Employee Confidentiality and Invention Assignment.

(a) Supplier acknowledges and agrees that, with respect to any past or current employee, staff, contractor, subcontractor or other agent of Supplier or its Affiliates who has conducted services or activities related to the development, manufacture or supply of the Product for or to Customer (collectively, the "**Supplier Employees**"), Supplier or its Affiliate has entered into a binding written arrangement(s) with each such Supplier Employee that requires: (i) that such Supplier Employee shall, at a minimum, keep the Confidential Information of Customer confidential and only use such Confidential Information to conduct permitted activities for Customer under Supplier's employment; and (ii) that such Supplier Employee assign to Supplier all of its right, title and interest in and to any inventions (including, without limitation, know-how, improvements, ideas, information, materials and processes) and all intellectual property rights therein that such Supplier Employee, alone or jointly with others, conceives, develops or reduces to practice during their period of employment or work with Supplier or its Affiliate.

(b) Supplier further covenants and agrees that, (i) with respect to any future Supplier Employee, Supplier or its Affiliate shall enter into a binding written arrangement with such Supplier Employee as set forth in Section 12.5(a) and (ii) with respect to any binding written arrangement referred to in this Section 12.5(b) or Section 12.5(a), Supplier shall enforce, to the fullest extent permitted under Applicable Law, the terms and provisions of such arrangement.

12.6. Duration of Obligation

Unless otherwise agreed by the Parties in writing, the obligations of the Parties relating to Confidential Information set out in this Article 12 shall survive the termination of this Agreement for a period of [***].

Article 13 Representations, Warranties and Covenants

13.1. Supplier's Representations, Warranties and Covenants

Supplier hereby represents, warrants and covenants to Customer as follows:

(a) Supplier has been duly organized and is validly subsisting and in good standing in its jurisdiction of organization and has the power to carry on the business as now being conducted by it;

(b) the execution, delivery and performance of this Agreement by Supplier have been duly authorized by all requisite corporate action and do not require any shareholder action or approval;

(c) Supplier has the right and authority to enter into this Agreement and perform its obligations hereunder, and this Agreement is a legal and valid obligation binding upon Supplier and enforceable in accordance with its terms;

(d) Supplier has not made and shall not make any commitments to Third Parties inconsistent with or in derogation of Supplier's obligations under this Agreement and Supplier is to its knowledge not subject to any obligations that would prevent it from entering into or carrying out its obligations under this Agreement, and Supplier's compliance with the terms and provisions hereof does not and shall not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a Product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter or operative documents or by-laws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) Supplier shall comply with all Applicable Law relating to its activities under this Agreement;

(f) all Product delivered to Customer under this Agreement shall have been Manufactured, stored and shipped in a competent fashion in accordance with the Master Batch Record, the Product Specifications, this Agreement, the Quality Agreement, Applicable Law and cGMP Requirements by qualified personnel and, to Supplier's knowledge, shall be free from defects;

(g) the Facilities, including equipment, systems, utilities and services, complies with cGMP Requirements for the Manufacture of the Product under this Agreement;

(h) the Facilities and Supplier's procedures and processes in the Facilities are in compliance with Applicable Law, including applicable environmental, health and safety requirements, for the Manufacture of the Product under this Agreement;

(i) Supplier does not, at any time from and after the Effective Date, retain or use the services of (i) any person debarred under 21 U.S.C. § 335a or (ii) any person who has been convicted of a crime as defined under the FD&C Act, in each case in any capacity associated with or related to the Manufacture or supply of Product or any service rendered to Customer under this Agreement or the Quality Agreement;

(j) all Product supplied by Supplier under this Agreement shall be delivered by it free and clear of any security interests, liens, claims, pledges or encumbrances of any kind or nature except for such as are created by Customer; and

(k) all records and reports required to be maintained by Supplier under cGMP Requirements shall be accurate and complete in all material respects.

In no event shall Customer seek to recover a refund for, or replacement to, an Out Of Specification Product due to Supplier's breach of Sections 13.1(f), 13.1(g) or 13.1(h) except pursuant to Article 8.

13.2. Customer's Representations, Warranties and Covenants

Customer hereby represents, warrants and covenants to Supplier as follows:

(a) Customer has been duly organized and is validly subsisting and in good standing in its jurisdiction of organization and has the power to carry on the business as now being conducted by it;

(b) the execution, delivery and performance of this Agreement by Customer have been duly authorized by all requisite corporate action and do not require any shareholder action or approval;

(c) Customer has the right and authority to enter into this Agreement and perform its obligations hereunder, and this Agreement is a legal and valid obligation binding upon Customer and enforceable in accordance with its terms;

(d) Customer has not made and shall not make any commitments to Third Parties inconsistent with or in derogation of Customer's obligations under this Agreement and Customer is not subject to any obligations that would prevent it from entering into or carrying out its obligations under this Agreement, and Customer's compliance with the terms and provisions hereof does not and shall not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a Product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter or operative documents or by-laws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) Customer shall comply with all Applicable Law relating to its activities under this Agreement; and

(f) to Customer's knowledge, [***].

13.3. No Other Warranty

THE WARRANTIE SET OUT IN SECTIONS 13.1 AND 13.2 ARE THE SOLE WARRANTIES MADE BY EITHER PARTY TO THE OTHER AND TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE PARTIES HEREBY DISCLAIM ANY AND ALL OTHER WARRANTIES, REPRESENTATIONS OR GUARANTEES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, REGARDING THE PRODUCT OR ANY OTHER MATERIALS OR SERVICES TO BE SUPPLIED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

13.4. No Consequential Damages and Limitation of Liability

(a) **Consequential Damages**. EXCEPT FOR [***], IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL OR INDIRECT DAMAGES, OR LOST PROFITS, HOWEVER CAUSED, REGARDLESS OF WHETHER SUCH CLAIM IS BASED ON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT TORT OR OTHER THEORY. THIS LIMITATION SHALL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

(b) Limitation of Liability.

(i) EXCEPT AS SET FORTH BELOW IN SECTION 13.4(b)(ii) AND SECTION 13.4(b)(iii), IN NO EVENT SHALL SUPPLIER'S LIABILITY,

HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, BE GREATER THAN, PER CLAIM OR SERIES OF CLAIMS ARISING FROM THE SAME CAUSE OF ACTION, [***].

(ii) WITH RESPECT TO [***], IN NO EVENT SHALL A PARTY'S LIABILITY, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, BE GREATER THAN, PER CLAIM OR SERIES OF CLAIMS ARISING FROM THE SAME CAUSE OF ACTION, [***].

(iii) WITH RESPECT TO [***], IN NO EVENT SHALL SUPPLIER'S LIABILITY, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, BE GREATER THAN, PER CLAIM OR SERIES OF CLAIMS ARISING FROM THE SAME CAUSE OF ACTION, [***].

(iv) [***]

Article 14 Indemnification

14.1. Indemnification of Supplier

Customer shall indemnify, defend and hold harmless Supplier and its officers, directors, agents, servants and employees against any and all actions, claims, demands, proceedings, suits, losses, damages, costs and expenses (including reasonable legal fees) of Third Parties (in this Article 14, "**Claims**") (including Claims for personal injury or death) to the extent such Claims result from or arise out of [***], except, in each case of clause (a) and (b), to the extent Supplier has an obligation to indemnify Customer pursuant to Sections 14.2 or 14.3.

14.2. Indemnification of Customer

Supplier shall indemnify, defend and hold harmless Customer and its Affiliates and Customer Licensees, and their respective officers, directors, agents, servants, employees and consultants against any and all Claims (including Claims for personal injury or death) to the extent such Claims result from or arise out of [***], except, in each case of clause (a) and (b), to the extent Customer has an obligation to indemnify Supplier pursuant to Sections 14.1 or 14.3.

14.3. [***]

[***]

14.4. Indemnification Procedure

The indemnities contained in this Article 14 shall be conditional on compliance with the terms and conditions set out in this Section 14.4. The indemnifying Party shall have the option to defend, contest, or otherwise protect against any such Claims at its own cost and expense provided that the party seeking indemnification (the "**Indemnitee**") regarding any such Claims gives written notice to the indemnifying Party promptly after receiving notice of said Claims. If the indemnifying Party chooses to defend Claims, the Indemnitee may, but shall not be obligated to, participate at its own expense in a defense thereof by counsel of its own choosing, but the indemnifying Party shall be entitled to control the defense unless the Indemnitee has relieved the indemnifying Party from liability with respect to the particular matter. If the indemnifying Party fails to timely defend, contest, or otherwise protect against any such Claims, the Indemnitee may defend, contest, or otherwise protect against the same,

and subject to the terms of this Section 14.4 make any reasonable compromise or settlement thereof and recover the entire costs thereof from the indemnifying Party, including reasonable legal fees and costs and disbursements, and all amounts paid as a result of such Claims or the compromise or settlement thereof; provided, however, that if the indemnifying Party undertakes the timely defense of such matter, the Indemnitee shall not be entitled to recover from the indemnifying Party for its costs incurred in the defense thereof. The Indemnitee shall cooperate and provide such assistance as the indemnifying Party may reasonably request in connection with the defense of the matter subject to indemnification. An indemnifying Party may not settle a Claim, without the consent of the indemnified Party, if such settlement would (a) impose any obligation on the indemnified Party, (b) not include a full release of claims with respect to the indemnified Party, (c) require the indemnified Party to submit to an injunction or otherwise limit the indemnified Party's rights under this Agreement or otherwise. Any payment made by an indemnifying Party to settle any such Claim shall be at its (or its insurer's) own cost and expense.

Article 15 Insurance

15.1. Insurance Coverage

Customer and Supplier each represent that they are sufficiently insured against any liability arising under this Agreement. Further, Supplier shall at a minimum retain [***].

15.2. Evidence of Insurance

Each of Customer and Supplier shall, upon request by the other, provide the other Party with a copy of all insurance policies maintained under this Article 15 relating to the Manufacture of the Product in bulk quantities and the facilities therefor and shall notify the other Party in writing at least [***] prior to the cancellation of or any material change to such insurance policies. Each Party may request that the other Party procure and maintain such additional insurance coverage relating to the Manufacture of the Product and the facilities therefore as may be reasonably necessary in respect of the Parties' respective obligations under this Agreement. If additional insurance coverage is requested by either Party, then the Parties will discuss in good faith and determine whether a general price adjustment of Product in Exhibit C is required.

Article 16 Legal and Regulatory

16.1. Compliance with Laws

(a) Each Party shall, in connection with its obligations, rights and duties under this Agreement and in Manufacturing, handling, storage, loading, shipping, using, commercializing, reselling and distributing the Product:

(i) comply with all Applicable Law or other requirements applicable to such Party's business; and

(ii) subject to subsection (b) below, obtain and maintain in full force and effect all applicable licenses, permits, certificates, authorizations or approvals from local governmental authorities necessary to conduct its business and the activities contemplated under this Agreement. Such licences or certificates are to be provided to the other Party on request.

(b) Customer shall be responsible for obtaining all necessary import or export licenses or permits and for the payment of all import or export fees, taxes or duties in connection with the purchase or delivery of the Product under this Agreement. Supplier shall reasonably cooperate with Customer in connection with obtaining necessary import or export licenses or permits.

16.2. Maintenance of Records

Supplier shall maintain adequate books and records and retention samples consistent with cGMP Requirements and any other Applicable Law and requirements of applicable governmental or regulatory authorities, in respect of test records, samples and associated support data for all Batches of Product Manufactured by Supplier sufficient to substantiate and verify Supplier's duties and obligations under this Agreement for [***] from the expiration date of the respective Product Batch and for non-Batch records for [***] after final payment under this Agreement. After that time, Supplier shall notify Customer of any intent to destroy cGMP Requirement records related to Customer Product, giving Customer the opportunity to obtain the records.

16.3. Notice of Reports

Supplier shall provide to Customer within [***] of receipt by Supplier copies of all Product-specific portions of any reports of any governmental or regulatory authority including, without limitation, any Facility-specific reports solely to the extent applicable to the Product or Manufacturing Process, FDA Form 483 observations, FDA warning letters or other correspondence from the FDA or equivalent correspondence from another Applicable Regulatory Authority; provided that Supplier may redact any information from such reports subject to confidentiality obligations and not related to the Product.

16.4. Drug Master Files

Supplier shall routinely update and keep current all information pertinent to maintain the Drug Master Files relating to the Manufacture of the Product at the production site of Supplier. Supplier shall fully support and reasonably assist Customer with its filing of any application with respect to the Product with any Applicable Regulatory Authority at Customer's expense.

16.5. Compliance with Regulatory Standards

Supplier shall be responsible for Manufacturing the Product in compliance with Applicable Law, cGMP Requirements and the standards of any other applicable governmental or regulatory authority. Each Party shall provide reasonable assistance to the other, at no charge, if necessary to respond to audits, inspections, inquiries, or requests of any Applicable Regulatory Authority. Supplier shall advise Customer immediately if Supplier receives notice of an impending inspection related to a Product or if an authorized agent of any Applicable Regulatory Authority or other governmental agency provides advance notice of any investigation, inspection or visit to a Facility. In such event, Supplier shall permit, to the extent permitted by Applicable Law, Customer or its representatives to be present during such visit, at Customer's expense. Upon Customer's request, Supplier shall provide Customer with a copy of any report issued by such Applicable Regulatory Authority following such visit.

16.6. Inspection

Supplier shall allow monitoring of the Facilities as set forth in Section 3.6 and inspections or audits as provided for in the Quality Agreement. Supplier shall make available to Customer

all relevant records and reports and Customer shall have the right to copy all Product related records and reports. The frequency of such audits as well as the response time with respect to audit findings shall be governed by the Quality Agreement.

Article 17 Recalls

17.1. Safety

Supplier shall provide Customer with reasonable co-operation to help Customer investigate adverse events or product complaints involving or related to the Product. The cost and expense of any testing undertaken by Supplier at Customer's request shall be borne by [***].

17.2. Recalls

If either Party has grounds to recommend a Recall or otherwise receives a notification or information which might result in a Recall, the Party recommending such Recall or receiving such notification or information shall immediately notify the other Party in writing. Subject to Applicable Law, Customer and its designees shall have the sole responsibility to implement any Recall of the Product or any intermediate or finished product containing the Product and the sole right to make all final decisions regarding any such Recall. Supplier shall reasonably cooperate with Customer and its designees in implementing any such Recall, at Customer's expense.

17.3. Replacement Shipments

In the event of any Recall or Seizure with respect to the Product during the Term of this Agreement, Supplier shall, upon the written request of Customer, as soon as reasonably possible, supply replacement Product to Customer in an amount sufficient to replace the amount of Product Recalled or Seized, at the applicable then current Fees for Product under this Agreement. If Customer makes such written request, Customer shall issue a Purchase Order in this regard which Supplier is obliged to accept. Supplier agrees to use commercially reasonable efforts to supply such replacement Product pursuant to the new Purchase Order as soon as possible (but in no event other than in accordance with the [***] lead time required pursuant to Section 6.1); provided, however, if the Recall or Seizure is caused by [***].

Article 18 Termination

18.1. Termination

This Agreement is effective as of the Effective Date and shall expire in accordance with Section 2.1, unless, upon the occurrence of any of the following events, this Agreement is earlier terminated in accordance with this Section 18.1:

(a) After the Initial Term, either Party delivers written notice of termination to the other Party, which termination shall be effective [***] from the date of such termination notice;

(b) Customer delivers written notice of termination to Supplier at any time during the Term in the event that: (i) Customer's annual sales demand of Product (tablets and vials in the annual equivalent of API) falls below a certain demand threshold, which shall be [***] as of the Effective Date through the end of the Initial Term and may be amended from time to time upon mutual agreement of the Parties; or (ii) if the Product is withdrawn from the Territory, as a result of any regulatory

actions or a material change in the business of Customer, which notice shall be effective [***] from the date of such termination notice;

(c) a Party makes a general assignment for the benefit of creditors, a court of competent jurisdiction declares a Party insolvent or bankrupt, or a petition in bankruptcy or under any insolvency law is filed by or against a Party and such petition is not dismissed within [***] after it has been filed, and the other Party delivers written notice of termination to such Party, which termination shall be effective immediately upon delivery of such written notice;

(d) a Party breaches a material provision of this Agreement (which, with respect to Supplier shall include, without limitation, a breach of Section 3.8 and any material failure of supply under Section 6.5, except in the event that Supplier's breach was caused by a failure of Customer to deliver Customer Materials to Supplier on the timeline required by this Agreement or to deliver Customer Materials that conform to the Customer Material Specifications at the time of delivery to Supplier, and any breach of Supplier's confidentiality and non-use obligations), and the other Party delivers written notice of termination to such breaching Party:

(i) if the breach is not cured within [***] after written notice thereof to the Party in default; or

(ii) if the breach is of a type that cannot be cured within [***], if a cure is not promptly commenced and diligently pursued until complete remediation but in any case after [***] unless otherwise agreed in writing between the Parties;

(e) any governmental law, regulation or order is adopted and made effective which would make performance of a Party's obligations under this Agreement impossible or commercially impracticable, and such Party delivers written notice of termination to the other Party, which termination shall be effective immediately upon delivery of such written notice; or

(f) Customer has the right to terminate under Section **Error! Reference source not found.**, which termination shall be effective [***] after delivery of written notice to Supplier.

18.2. Consequences of Termination

On expiration or the effective date of termination of this Agreement, if earlier:

(a) both Parties shall be released from all obligations and duties imposed or assumed hereunder, except obligations and liabilities previously accrued and as expressly provided by this Agreement, including, without limitation, those provisions which expressly survive termination or expiration of this Agreement;

(b) all Rights granted by Customer to Supplier under Section 11.3 shall immediately revert to Customer, provided that Supplier may continue to use any such Rights in order to fulfil its surviving obligations under Section 18.5, and only for such purpose;

(c) Supplier shall provide to Customer, to the extent they exist, copies of:

(i) Supplier's Manufacturing Batch records and analytical reports relating to the Product; and

(ii) any other documents required to be delivered pursuant to this Agreement or otherwise reasonably requested by Customer; provided that any documents requested by Customer shall be provided at Customer's expense;

(d) Unless this Agreement is terminated by Customer pursuant to Section 18.1(d) above, all Purchase Orders and Scopes of Work shall automatically be deemed terminated by Customer and Supplier shall be compensated for final Product already produced or Services already rendered in accordance with this Agreement and, for Product or Services not yet produced or rendered, as the case may be, Supplier shall be entitled to its fees, expenses and costs as set forth in Sections 6.4 and 6.6. Additionally, Customer shall be entitled to request that (i) all Product or works in process for which Customer has compensated Supplier and (ii) all Customer Materials be shipped to Customer in accordance with the provisions of Section 7.2(d). If this Agreement is terminated by Customer pursuant to Section 18.1(d) as a result of Supplier's breach, then, Customer shall be able to elect whether Purchase Orders or Scopes of Work not yet completed at the date of termination or expiration should continue in force, subject to the terms and conditions herein; and

(e) Supplier shall promptly cooperate with Customer to transfer and transition supply of the Product to a Third Party supplier. Upon Customer's request, Supplier shall cooperate with Customer in the transfer of technology and know-how necessary to Manufacture Product to such Third Party supplier, including providing Customer and the Third Party supplier with reasonable access to the Facilities and consulting services related to Manufacturing of the Product. Supplier shall conduct such activities at Customer's expense paid in advance.

18.3. Return of Samples

On expiration or earlier termination of this Agreement, unless otherwise instructed by Customer, Supplier shall, within [***], return to Customer all samples or other supplies of the Product (for which Supplier has been paid) in its possession or control in any form, with the exception of any samples such as retention samples that Supplier may be required to keep according to Applicable Law. The cost of returning any such supplies shall:[***]

18.4. Return of Confidential Information

On expiration or earlier termination of this Agreement, unless otherwise agreed between the Parties, each Party shall:

(a) promptly cease all use of the Confidential Information of the other Party and ensure that its corporate counsel, employees and contractors cease all use thereof; and

(b) upon written request of the other Party,

(i) return to the other Party all original copies of the Confidential Information of the other Party in its control or possession, subject to the retention of one (1) complete copy for archival purposes and to satisfy any applicable legal requirements; and

(ii) except for back-up copies generated by the recipient Party's IT system, destroy any and all copies or other reproductions or extracts of the Confidential Information of the other Party and all other documents, computer files, memoranda, notes or other writings prepared based on such Confidential Information subject to subsection (i) above.

18.5. Survival

Except as otherwise provided herein or agreed in writing between the Parties, expiration or early termination of this Agreement shall not relieve either Party of its obligations incurred prior to such expiration or early termination, including the obligation to Manufacture and deliver the Product under Purchase Orders placed by Customer and accepted by Supplier prior to the effective date of expiration or earlier termination, and the obligation to pay Fees in respect thereof. In addition, the following provisions shall survive any expiration or early termination of this Agreement in accordance with the terms of such provision; provided that if there is no express expiration or termination of an obligation or a right under a surviving provision, such provision or right shall continue to survive, subject to Applicable Law[***]:

Article 1 (Interpretation); Section 2.2 (Effect of Expiration on Purchase Orders); Section 5.3 (Retention Samples); Section 8.2 (Dispute of Rejected Product) and Section 8.3(b) (Remedies) (in each case, solely with respect to Latent Defects); Article 9 (Fees) (solely with respect to amounts accrued prior to termination); Article 11 (Intellectual Property) (other than Section 11.3 (Grant of License by Customer)); Article 12 (Confidentiality & Publicity) (for [***] after termination); Section 13.3 (No Other Warranty); Section 13.4 (No Consequential Damages and Limitation of Liability); Article 14 (Indemnification); Article 15 (Insurance); Section 16.2 (Maintenance of Records); Section 16.4 (Drug Master Files); Section 16.6 (Inspection); Sections 17.2 (Recalls); Sections 18.2 (Consequences of Termination), 18.3 (Return of Samples) and 18.4 (Return of Confidential Information); this Section 18.5 (Survival); and Article 19 (Miscellaneous) (except Sections 19.2 and 19.5).

Further, Article 8 (Acceptance of Shipments) shall survive any expiration or termination of this Agreement solely with respect to shipments of Product shipped prior to the effective date of expiration or termination.

Article 19 Miscellaneous

19.1. Assignment; Inurement

This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their successors and permitted assigns. Supplier shall not assign this Agreement, in whole or in part, to any person without the prior written consent of Customer, except to a Third Party which acquires all, or substantially all, of Supplier's business or assets, whether through merger or otherwise.

Customer shall be entitled to assign this Agreement, in whole or in part, to any person without the consent of Supplier, provided that (i) such person acquires all, or substantially all, of Customer's business or assets with respect to the Product, whether through merger or otherwise; (ii) such person is an Affiliate of Customer or a Customer Licensee; or (iii) Customer remains liable for any payments Supplier is or shall be entitled to under this Agreement. Customer shall not assign this Agreement, in whole or in part, to any other person without the prior written consent of Supplier, not to be unreasonably withheld, conditioned or delayed.

19.2. Change of Control

During the Term, Supplier shall promptly notify Customer in writing if at any time a Change of Control shall occur as to Supplier, such notification to be given no later than [***] following such Change of Control. [***]

19.3. Counterparts

This Agreement may be executed in any number of counterparts each of which shall be deemed to be an original and all of which taken together shall be deemed to constitute one and the same instrument. This Agreement, following its execution, may be delivered via PDF copies or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

19.4. Dispute Resolution

Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be referred first to senior management of the Parties for amicable resolution. In the event that amicable resolution has not been achieved within [***], then either Party may seek resolution through confidential arbitration in accordance with the ICC Rules of Arbitration. The arbitration hearing shall be held as soon as practicable following submission to arbitration. The arbitration hearing shall be held in Delaware, United States of America. The Parties shall request that the arbitration panel render a formal, binding non-appealable resolution and award on each issue as expeditiously as possible. In any arbitration, the prevailing Party shall be entitled to reimbursement of its reasonable attorneys' fees and the Parties shall use all reasonable efforts to keep arbitration costs to a minimum. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.

19.5. Force Majeure

Any delay or inability to perform any of the duties or obligations of either Party caused by an event outside the affected Party's reasonable control shall not be considered a breach of this Agreement, and unless provided to the contrary herein, the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include, without limitation: acts of God; any governmental act or regulation; insurrections; riots or civil disturbance; acts of war; embargoes; labor disputes at facilities of Material suppliers, including strikes, lockouts, job actions, or boycotts; fires; explosions; terrorist attacks; floods; or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. In order to take the benefit of this Section 19.5, the Party so affected shall give prompt notice [***] to the other Party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. If performance is affected for a cumulative period of more than [***] period, the non-affected Party may terminate this Agreement immediately by notice in writing to the affected Party.

19.6. Performance

Each Party agrees to perform its obligations under this Agreement, including under any Scope of Work, in a timely manner. Supplier shall allocate adequate resources to execute its obligations under this Agreement, including under each Scope of Work. Supplier represents and warrants that all Services shall be performed by qualified personnel in accordance with the highest industry standards.

19.7. Further Assurances

The Parties shall both execute and deliver such further instruments and do such further acts as may be required to implement the intent of this Agreement.

19.8. Independent Contractors

Supplier and Customer shall be independent contractors and shall not be deemed to be partners, joint venturers or each other's agents under this Agreement, and neither Party shall have the right to act on behalf of the other except as is expressly set forth in this Agreement.

19.9. Injunctions

Each Party agrees that the other Party may be irreparably damaged if any provision of this Agreement is not performed in accordance with its terms. Accordingly, notwithstanding Section 19.4, each Party shall be entitled to apply for an injunction or injunctions to prevent breaches of any of the provisions of this Agreement by the other Party, without showing or proving any actual or threatened damage, notwithstanding any rule of law or equity to the contrary, and may specifically enforce such provisions by an action instituted in a court having jurisdiction. These specific remedies are in addition to any other remedy to which the Parties may be entitled at law or in equity.

19.10. Notices

Unless otherwise provided herein, any notice required or permitted to be given hereunder or any proposal for any modification of this Agreement (collectively referred to as the "**Correspondence**") shall be mailed by overnight mail, certified mail postage prepaid, or delivered by hand to the Party to whom such Correspondence is required or permitted to be given hereunder at the addresses set out below. If delivered by hand, any such Correspondence shall be deemed to have been given when received by the Party to whom such Correspondence is given.

If to Supplier:

CARBOGEN AMCIS AG
Hauptstrasse 171
CH 4416 Bubendorf
Switzerland
Attention: [***]
Telephone:[***]

If to Customer:

Paratek Pharmaceuticals, Inc.
1000 First Avenue, Ste. 200,
King of Prussia, PA 19406
USA
Attention: [***] Sr. Vice President, Technical Operations
Phone: [***]

With copy to:

Paratek Pharmaceuticals, Inc.
1000 First Avenue, Ste. 200,
King of Prussia, PA 19406
USA
Attention: General Counsel
Phone: [***]

Either Party may change the address to which any Correspondence to it is to be addressed by notification to the other Party as provided herein.

19.11. Entire Agreement

This Agreement, the Quality Agreement and all Exhibits attached hereto (as the same may be amended from time to time by the written agreement of the Parties) constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all other documents, agreements, verbal consents, arrangements and understandings between the Parties with respect to the subject matter hereof. This Agreement shall not be amended orally, but only by an agreement in writing, signed by both Parties that states that it is an amendment to this Agreement. For the avoidance of doubt, as of the Effective Date, this Agreement shall replace the Outsourcing Agreement; provided, however, that this Agreement shall not relieve either Party of its obligations incurred under the Outsourcing Agreement or otherwise prior to the Effective Date of this Agreement, including any confidentiality obligations.

19.12. Severability

If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

19.13. Waiver

No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by an authorized representative of the Parties hereto. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

[*Signature page follows.*]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed by its duly authorized officer as of the Effective Date.

PARATEK PHARMACEUTICALS, INC.
by its authorized signatory:

/s/ Jason Burdette
Name: Jason Burdette
Title: SVP Technical Operations
Date: 7/13/2021

CARBOGEN AMCIS AG
by its authorized signatory:

/s/ Dr. Stephanie Quintes
Name: Dr. Stephanie Quintes
Title: Senior Head of Commercial Products
CARBOGEN AMCIS AG
Date: 14. Jul. 2021

CARBOGEN AMCIS AG
by its authorized signatory:

/s/ Dr. Anton Gayring
Name: Dr. Anton Gayring
Title: Senior Head of Development
CARBOGEN AMCIS AG
Date: 14. Juli 2021

Exhibit A – Description of Product

[***]

Exhibit B – Chemical Synthesis

[***]

Exhibit C – Fee Schedule

[***]

Exhibit D – Certificate of Analysis and Certificate of Compliance

[***]

APPENDIX A

U.S. GOVERNMENT REQUIREMENTS FOR COMMERCIAL SUBCONTRACTS UNDER PRIME CONTRACT NO. 75A50120C00001

This Agreement between PARATEK and CARBOGEN AMCIS AG (the "Service Provider") is a commercial-item subcontract under prime contract no. 75A50120C00001 between PARATEK and the Biomedical Advanced Research and Development Authority ("BARDA"). For clarity, this Appendix A is part of the Commercial Supply Agreement between PARATEK and CARBOGEN AMCIS AG dated July 14, 2021. As a result, this Appendix Agreement between PARATEK and CARBOGEN AMCIS AG is also subject to the following Federal Acquisition Regulation ("FAR") clauses, which are hereby incorporated into this Agreement by reference with the force and effect as though set forth in full text herein. The full text of FAR clauses may be accessed electronically at http://www.aquisition.gov; FAR clauses may be accessed at http://www.ecfr.gov. The additional clauses included in full text below are also incorporated by reference into this Agreement.

Unless otherwise noted with respect to a particular clause, the following changes in terminology will apply to each clause, regardless of capitalization, when consistent with a reasonable interpretation of the clause, which properly expresses the relationship between PARATEK and Service Provider.

The term "government" or "USG" means "PARATEK."
The term "contractor" or "offeror" means "Service Provider."
The term "contract" or "grant" means "this Agreement."
The term "contracting officer" or "contracting officer's representative" means "authorized PARATEK representative."
The term "subcontract" means "lower-tier agreement under this Agreement."

FAR CLAUSE	TITLE
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Oct 2010)
52.203-13	Contractor Code of Business Ethics and Conduct (Oct 2015) [references to "Government" and "Contracting Officer" remain unchanged]
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) [references to "Government" remain unchanged]
52.204-21	Basic Safeguarding of Covered Contractor Information Systems (Jun 2016) [references to "Government" remain unchanged]
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) [references to "Government" and "Contracting Officer" remain unchanged; Service Provider will timely provide PARATEK with a copy of any notice that Service Provider provides to the Government under this clause]
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020) [references to "Government" and "Contracting Officer" remain unchanged; Service Provider will timely provide PARATEK with a copy of any notice that Service Provider provides to the Government under this clause]-

FAR CLAUSE	TITLE
52.209-6	Protecting the Government Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Oct 2015)
52.222-50	Combating Trafficking in Persons (Jan 2019) [PARATEK may take appropriate action against Service Provider, including termination of this Agreement, for violation of paragraph (b); if a certification is required under paragraph (h)(5), the Service Provider will submit the certification at FAR 52.222-56 before award and during performance of this Agreement]
52.227-14	Rights in Data—General (May 2014), Alt II (Dec 2007) [Limited Rights Notice; paragraph (a) 75A50120C00001 (unless another number is identified by PARATEK); Service Provider will provide data or analyses generated with Agreement funding upon PARATEK's request at no additional cost; to the extent that this Agreement specifies different intellectual property rights as between Service Provider and PARATEK, the Agreement will control subject to any rights provided to the U.S. Government under the applicable PARATEK contract(s) with the U.S. Government] [***]
52.244-6	Subcontracts for Commercial Items (Jan & Aug 2019)

Additional Clauses Included in Full Text

The following additional clauses are included in this Agreement in full text, unless otherwise indicated below. The interpretive guidelines set forth above do not apply to each of the clauses included below.

1. **EXCLUDED STATUS**. Pursuant to FAR 52.209-6, Service Provider represents that to the best of their knowledge, as of the date of the effective date of the Agreement, neither Service Provider or its subcontractor(s), nor any of Service Provider's or its subcontractor's respective principals, are debarred, suspended, or proposed for debarment by the U.S. Government. Service Provider must confirm this representation on the effective date of this Agreement if the effective date of this Agreement occurs after the date on which Service Provider executes this Agreement.

2. **U.S. GOVERNMENT REPORTING**. No confidentiality provision included in this Agreement may be construed to prohibit or otherwise restrict Service Provider, as a subcontractor of PARATEK under a U.S. Government contract, from lawfully reporting waste, fraud, or abuse to a designated investigative or law enforcement representative of the federal department or agency authorized to receive such information under the procurement involving PARATEK's agreement with BARDA.

3. **U.S. GOVERNMENT SITE VISITS, AUDITS, INSPECTIONS, AND COMMUNICATIONS**. At the U.S. Government's request, PARATEK and the U.S. Government together will have the right to conduct site visits, audits, and inspections at Service Provider's facilities relating to PARATEK's performance of this Agreement, including for the purpose of inventorying [***]. If PARATEK or the U.S. Government identifies any issues during the visit, Service Provider will prepare a report describing the issues and identifying potential solutions. Service Provider will provide the report to PARATEK for review within seven business days of being notified of any issues. Once

corrective action is taken in consultation with PARATEK, Service Provider will provide PARATEK with a follow-up report within seven business days.

To the extent permitted by law, Service Provider will also make commercially reasonable efforts to provide PARATEK with notice [***] of any arrival of U.S. Government personnel to conduct site visits or audits at Service Provider's facility that is announced to cover work performed under this Agreement or [***] when the work performed under this Agreement comes into focus of such an audit. Service Provider will also provide PARATEK with a plan for addressing any areas of non-conformance with regulatory requirements identified in such a site visit or audit, as well as a complete copy of any Form 483 provided to Service Provider by the U.S. Food and Drug Administration in connection with such a site visit or audit. Service Provider will permit U.S. Government representatives identified by PARATEK to be present at the final debrief associated with such a site visit or audit.

During any audit by U.S. Government personnel, Service Provider will provide its standard operating procedures relating to performance of this Agreement directly to the U.S. Government upon the U.S. Government's request. Extensive requests for copies or translations will be at PARATEK's expense based on a mutually agreed Work Order. Service Provider will also make commercially reasonable efforts to provide PARATEK with copies of any correspondence between Service Provider and the U.S. Food and Drug Administration relating to performance under this Agreement within [***].

4. **NO SUPPORT OF TERRORISM**. Service Provider acknowledges that U.S. executive orders and laws, including but not limited to Executive Order 13224 and Public Law 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 Service Provider to ensure compliance with these executive orders and laws.

5. **[***]

6. **U.S. EMPLOYEES**. Service Provider acknowledges that certain U.S. laws may apply to the extent that Service Provider performs work under this Agreement with employees that have been recruited or transferred from the United States.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES
		1 5

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00002	See Block 16C	[***]	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
Washington DC 20201 Room 640-G 200 Independence Ave., S.W. ASPR-BARDA	ASPR-BARDA	Washington DC 20201 200 INDEPENDENCE AVE, S.W. BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT US DEPT OF HEALTH & HUMAN SERVICES ASPR-BARDA	ASPR-BARDA

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)		9A. AMENDMENT OF SOLICITATION NO.
PARATEK PHARMACEUTICALS INC 1549007 75 PARK PLZ FL 4 BOSTON MA 021163934	(x)	9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C0000
		10B. DATED *(SEE ITEM 13)* 12/18/2019

CODE 1549007 FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase:$43,483.00

2021.1990001.25106

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.243-2 Alt V, and FAR 43.103(a) Bilateral: Mutual Agreement of the Parties
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not X is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 33-0960223
DUNS Number: 076333934
See Block 14 supplemental pages to Modification P00002 for additional information.
Appr. Yr.: 2021 CAN: 1990001 Object Class: 25106
Period of Performance: 07/30/2021 to [***]

Add Item 9 as follows:

9 ASPR-21-01796-CLIN 9 option funding to distribute 43,483.00
2500 courses of procured Nuzyra PO 75A50120C00001
Continued …

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
[***]		[***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/[***]	July 29, 2021	/s/[***]	2021.07.29

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	75A50120C00001/P00002	2	5

NAME OF OFFEROR OR CONTRACTOR

PARATEK PHARMACEUTICALS INC 1549007

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
(A)	(B)	(C)	(D)	(E)	(F)
	Obligated Amount: $43,483.00 Award Type: Cost Total Estimated Cost: $43,483.00				

SUMMARY OF CHANGES

Beginning with the effective date of this modification, the Government and Contractor mutually agree as follows:

1.) ARTICLE B.3. OPTIONS, is modified to incorporate CLIN 0009 for the Emergency Distribution of Procured Antibiotic from VMI and funding in the amount of $43,483.00.

2.) ARTICLE B.4 ADVANCE UNDERSTANDINGS is modified to include additional language under paragraph m, VMI.

3.) ARTICLE C.1. STATEMENT OF WORK, and SECTION J, LIST OF ATTACHMENTS is modified to incorporate revised Statement of Work, dated July 22, in its entirety.

4.) SECTION J, LIST OF ATTACHMENTS, is modified to incorporate the Vendor Managed Inventory Plan v.1 (June, 2021).

Obligated Funding - Cost Reimbursement CLINs			
	Cost	Fee	CPFF
CLIN 0001 (Base Award)	[***]	[***]	$ 21,525,559.00
CLIN 0004 (P00001)	[***]	[***]	$ 20,435,260.00
CLIN 0005 (P00001)	[***]	[***]	$ 76,774,872.00
CLIN 0009 (P00002)	[***]	[***]	$ 43,483.00
Subtotal	[***]	[***]	$ 118,779,174.00

Obligated Funding - Fixed Price CLINs	
	FFP
CLIN 0002 (Base Award)	$ 37,855,000.00

Total Funded	$ 156,634,174.00

ARTICLE B.3. OPTIONS is modified to incorporate CLIN 0009 as follows:

CLIN	**Period of Performance**	**Supplies/Services**	**Total Est. Cost**	**Fixed Fee**	**Total Cost Plus Fixed Fee**
0009	07/30/2021 to [***]	Emergency Distribution of Procured Antibiotics from VMI	[***]	[***]	$43,483.00

ARTICLE B.4. ADVANCE UNDERSTANDINGS is modified as follows:

m. VMI

[***]

I. In a small scale emergency situation, which may not receive a national emergency declaration, upon receiving a request for NUZYRA® drug product for distribution from the USG, the Contractor shall trigger the established communication chain to potentially trigger all or part of the emergency deployment strategies outlined in the VMI Distribution Plan and CLIN 0009.

II. Notification of Release of Product- Notification to release product under this Contract shall be provided in writing to the Contractor by the CO, or by an authorized representative designated by the CO.

III. The cost estimate listed in CLIN 0009 represents the best estimate, and Contractor can submit invoices for reimbursement of costs incurred in performing activities under CLIN 0009. Upon triggering of deployment actions the Contractor may seek additional reimbursement up to the actual costs incurred by providing justification and approval by CO.

ARTICLE C.1. STATEMENT OF WORK is modified as follows:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated July 22, 2021 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

SECTION J - LIST OF ATTACHMENTS is modified as follows:

1. Statement of Work, dated July 22, 2021, 11 pages
2. Invoice/Financing Instructions for Cost-Reimbursement Type Contracts
3. Invoice Instructions for Fixed-Priced Type Contracts
4. Sample Invoice Form
5. Report of Government Owned, Contractor Held Property, 1 page
6. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages
7. Paratek Intellectual Property, 20 Pages

8. VMI[***] Requirements, 3 Pages

9. Vendor Managed Inventory Plan v.1, 14 Pages

All other terms and conditions of this contract remain unchanged and in full force and effect.

END OF MODIFICATION P00002 to 75A50120C00001

ATTACHMENT 1

Statement of Work
75A50120C00001
Date: 7-22-2021

PREAMBLE

Independently and not as an agency of the Government, the Contractor shall be required to 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.

The Government reserves the right to modify the milestones, progress, schedule, budget, or deliverables to add or delete deliverables, process, or schedules i the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. The Government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to procure an antibiotic that can be used under Emergency Use Authorization (EUA) pre-approval or marketin authorization for the treatment and/or post-exposure prophylaxis treatment of pulmonary anthrax. The Contractor will develop NUZYRA® for Animal Ru licensure, with the objective of making it suitable for stockpiling and use to treat infections with B. anthracis. Once suitable regulatory authorization has been achieved or under an applicable stockpiling authority, NUZYRA® will be purchased and delivered to the [***] or these supplies will become part of a VM program managed by Paratek. Optional objectives cover activities to help secure the NUZYRA® supply chain, activities to support the commercia sustainability of NUZYRA® with the objective to ensuring continued supply, activities intended to expand the Animal Rule licenses of NUZYRA®, and furth purchases for VMI managed by Paratek. The scope of work for this contract includes preclinical, clinical, manufacturing and procurement activities that fall into the following areas: nonclinical activities; clinical activities; manufacturing activities; procurement activities and all associated regulatory, quality assurance, management, and administrative activities. The Research and Development (R&D) efforts and procurement of NUZYRA® will progress in specific stages th cover the base performance (CLINs 1 and 2) segment and six (6) option segments (CLINs 3 to 8) as specified in this contract. The Contractor must comple specific tasks required in each of the discrete work segments. The scope of work has been broken into the following phases which are discrete work segments:

1. CLIN 1: LATE STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)
2. CLIN 2: INITIAL PURCHASE, STORAGE AND DELIVERY OF ANTIBIOTIC AS FINAL DRUG PRODUCT (FDP)
3. CLIN 3: SUPPLEMENTAL LATE STAGE DEVELOPMENT FOR ANTHRAX

4. CLIN 4: BARDA SECURITY REQUIREMENTS, ON-SHORING COMMERCIAL MANUFACTURING [***]

5. CLIN 5: POST-MARKETING STUDY COMMITMENTS/ REQUIREMENTS FOR COMMERCIAL CABP AND ABSSSI INDICATIONS

6. CLIN 6: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

7. CLIN 7: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

8. CLIN 8: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

9. CLIN 9: EMERGENCY DISTRIBUTION OF THE PROCURED ANTIBIOTIC

1. CLIN 1: LATE STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)

The Contractor will continue to develop of NUZYRA® for the treatment of pulmonary Anthrax with the objective of obtaining approval through the FD Animal Rule.

[***]

2. CLIN 2: INITIAL PURCHASE, STORAGE AND DELIVERY OF ANTIBIOTIC AS FINAL DRUG PRODUCT (FDP)

The Contractor will supply 2,500 drug product treatment courses of NUZYRA® [***]

[***]

3. CLIN 3: SUPPLEMENTAL LATE STAGE DEVELOPMENT FOR ANTHRAX

[***]

4. CLIN 4: BARDA SECURITY REQUIREMENTS, ON-SHORING COMMERCIAL MANUFACTURING [***]

[***]

5. CLIN 5: POST-MARKETING STUDY COMMITMENTS/ REQUIREMENTS FOR COMMERCIAL CABP AND ABSSSI INDICATIONS

[***]

6. CLIN 6: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government a VMI or deliver such inventory to the ASPR[***] in the manner described in CLIN 2.

7. CLIN 7: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government a VMI or deliver such inventory to the ASPR[***] in the manner described in CLIN 2.

8. CLIN 8: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government a VMI or deliver such inventory to the ASPR[***] in the manner described in CLIN 2.

9. CLIN 9: EMERGENCY DISTRIBUTION OF PROCURED ANTIBIOTIC

The Contractor is to be prepared to deploy up to [***] treatment courses of drug product from existing product in VMI to the field in the United States in th event of a national emergency or a small scale emergency situation under an appropriate regulatory mechanism (e.g. EUA, IND or sNDA), following th agreed upon procedures between Contractor, BARDA[***]

Revised Timeline view of all CLINs provided in the SOW (3/26/2020)

[***]

Milestone	Deliverable	Success Criteria	Go/No-Go	Year/Qtr Achieved
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
			[***]	
**]	[***]		[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]
**]	[***]	[***]	[***]	[***]

ATTACHMENT 9

CLIN0002 Vendor Managed Inventory Plan for Paratek Pharmaceuticals

[Pursuant to Regulation S-K, Item 601(a)(5), this Attachment 9 setting forth the Vendor Managed Inventory Plan has not been filed. The Registrant agrees to furnish supplementally a copy of any omitted scheduled to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.]

[***]

103912510_9

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 of 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00003	See Block 16C	[***]	

6. ISSUED BY CODE ASPR-BARDA

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

7. ADMINISTERED BY *(If other than Item6)* CODE ASPR-BARDA

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

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

PARATEK PHARMACEUTICALS INC 1549007
PARATEK PHARMACEUTICALS, INC.
75 PARK PLZ FL 4
BOSTON MA 021163934

CODE 1549007 FACILITY CODE

(x)	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED *(SEE ITEM 11)*
x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00001
	10B. DATED *(SEE ITEM 13)* 12/18/2019

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase:$31,574,667.00

2021.1991073.25106

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 52.217-9 Option to Extend the Term of the Contract & FAR 43.103(a) Mutual Agreement of the Parties

E. IMPORTANT: Contractor ☐ is not X is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 33-0960223
DUNS Number: 076333934
The purpose of this modification is to exercise Option 2 and modify ARTICLE B.3. OPTIONS, ARTICLE C.1. STATEMENT OF WORK, ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR), and SECTION J LIST OF ATTACHMENTS accordingly.
Funds Obligated Prior to this Modification: $ 156,634,174
Funds Obligated with Mod #3: $ 31,574,667
Total Funds Obligated to Date: $ 188,208,841
Appr. Yr.: 2021 CAN: 1991073 Object Class: 25106

Change Item 3 to read as follows(amount shown is
Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
[***]	[***]

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ [***] *(Signature of person authorized to sign)*	9/23/2021	/s/ [***] *(Signature of Contracting Officer)*	2021.09.23

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	75A50120C00001/P00003	2	4

NAME OF OFFEROR OR CONTRACTOR

PARATEK PHARMACEUTICALS INC 1549007

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
(A)	(B)	(C)	(D)	(E)	(F)
	the obligated amount) :				
3	CLIN 0003 SUPPLEMENTAL DEVELOPMENT TO SUPPORT EUA OR LICENSURE OF TREATMENT and/or PEP OF ANTHRAX Obligated Amount: $31,574,667.00 Award Type: Cost-plus-fixed-fee Total Estimated Cost: $[***] Fixed Fee: $[***] Completion Form Period of Performance: 09/30/2021 to [***]				31,574,667.00

Total Obligated Funding

Obligated Funding - Cost Reimbursement CLINs			
	Cost	Fee	CPFF
CLIN 0001 (Base Award)	[***]	[***]	$21,525,559.00
CLIN 0003 (P00003)	**[***]**	**[***]**	**$31,574,667.00**
CLIN 0004 (P00001)	[***]	[***]	$20,435,260.00
CLIN 0005 (P00001)	[***]	[***]	$76,774,872.00
CLIN 0009 (P00002)	[***]	[***]	$43,483.00
Subtotal	**[***]**	**[***]**	**$150,353,841.00**

Obligated Funding - Fixed Price CLINs	
	FFP
CLIN 0002 (Base Award)	$37,855,000.00

Total Funded	**$188,208,841.00**

ARTICLE B.3. OPTIONS, is modified as follows:

Optional Cost Reimbursement CLINs					
CLIN	**Period of Performance**	**Supplies/ Services**	**Total Est. Cost**	**Fixed Fee**	**Total Cost Plus Fixed Fee ($)**
0003 (Option)	**09/30/2021 – [***]**	**Supplemental development to support EUA or licensure of treatment and/or PEP of anthrax**	**[***]**	**[***]**	**$31,574,667 (Funded)**
0004 (Option)	04/01/2020 – [***]	BARDA Security Requirements	[***]	[***]	$20,435,260 (Funded)
0005 (Option)	04/01/2020 – [***]	Post-Marketing Study Commitments/ Requirements for the authorized commercial indication including relabeling of approved drug in the ASPR[***] or VMI (this is an option that may or may not be exercised as required by the FDA)	[***]	[***]	$76,774,872 (Funded)
0009 (Option)	07/30/2021 – [***]	Emergency Distribution of Procured Antibiotics from VMI	[***]	[***]	$43,483.00 (Funded)

ARTICLE C.1. STATEMENT OF WORK is modified as follows:

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.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR), is modified as follows:

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

[***]
Contracting Officer's Representative
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[***]

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

[***]
Contracting Officer's Representative
Chief Antibacterials Branch
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[***]

Mailing Address:

200 C St.
O'Neill House Office Building (BARDA)
Washington, D.C. 20515

The alternate COR is responsible for carrying out the duties of the COR in the event that the COR can no longer perform his/her duties as assigned.

SECTION J – LIST OF ATTACHMENTS, is modified as follows:

1. Statement of Work, dated **September 9, 2021**, 11 pages

All other terms and conditions of this contract remain unchanged and in full force and effect.

END OF MODIFICATION P00003 to 75A50120C00001

ATTACHMENT 1

Statement of Work
Contract# 75A50120C00001
Date: 09/09/2021

PREAMBLE

Independently and not as an agency of the Government, the Contractor shall be required to 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.

The Government reserves the right to modify the milestones, progress, schedule, budget, or deliverables to add or delete deliverables, process, or schedules if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. The Government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to procure an antibiotic that can be used under Emergency Use Authorization (EUA) pre-approval or marketing authorization for the treatment and/or post-exposure prophylaxis treatment of pulmonary anthrax. The Contractor will develop NUZYRA® for Animal Rule licensure, with the objective of making it suitable for stockpiling and use to treat infections with *B. anthracis*. Once suitable regulatory authorization has been achieved or under an applicable stockpiling authority, NUZYRA® will be purchased and delivered to the [***] or these supplies will become part of a VMI program managed by Paratek. Optional objectives cover activities to help secure the NUZYRA® supply chain, activities to support the commercial sustainability of NUZYRA® with the objective to ensuring continued supply, activities intended to expand the Animal Rule licenses of NUZYRA®, and further purchases for VMI managed by Paratek. The scope of work for this contract includes preclinical, clinical, manufacturing and procurement activities that fall into the following areas: nonclinical activities; clinical activities; manufacturing activities; procurement activities and all associated regulatory, quality assurance, management, and administrative activities. The Research and Development (R&D) efforts and procurement of NUZYRA® will progress in specific stages that cover the base performance (CLINs 1 and 2) segment and six (6) option segments (CLINs 3 to 8) as specified in this contract. CLIN 9 was added immediately following the first delivery to provide funding to the contractor for distribution of USG-procured product held in VMI in the event of the small scale anthrax outbreak. The Contractor must complete specific tasks required in each of the discrete work segments. The scope of work has been broken into the following phases which are discrete work segments:

1. CLIN 1: LATE-STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)
2. CLIN 2: INITIAL PURCHASE, STORAGE AND DELIVERY OF ANTIBIOTIC AS FINAL DRUG PRODUCT (FDP)
3. CLIN 3: SUPPLEMENTAL DEVELOPMENT TO SUPPORT EUA OR LICENSURE OF TREATMENT and/or PEP OF ANTHRAX
4. CLIN 4: BARDA SECURITY REQUIREMENTS, ON-SHORING COMMERCIAL MANUFACTURING [***]

5. CLIN 5: POST-MARKETING STUDY COMMITMENTS/ REQUIREMENTS FOR COMMERCIAL CABP AND ABSSSI INDICATIONS
6. CLIN 6: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)
7. CLIN 7: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)
8. CLIN 8: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)
9. CLIN 9: EMERGENCY DISTRIBUTION OF THE PROCURED ANTIBIOTIC

1. CLIN 1: LATE-STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)

The Contractor will continue to develop of NUZYRA® for the treatment of pulmonary Anthrax with the objective of obtaining approval through the FDA Animal Rule.

[***]

2. CLIN 2: INITIAL PURCHASE, STORAGE AND DELIVERY OF ANTIBIOTIC AS FINAL DRUG PRODUCT (FDP)

The Contractor will supply 2,500 drug product treatment courses of NUZYRA® [***]

[***]

3. CLIN 3: SUPPLEMENTAL DEVELOPMENT TO SUPPORT EUA OR LICENSURE OF TREATMENT AND/OR PEP OF ANTHRAX

[***]

4. CLIN 4: BARDA SECURITY REQUIREMENTS, ON-SHORING MANUFACTURING, [***]

[***]

5. CLIN 5: POST-MARKETING STUDY COMMITMENTS/ REQUIREMENTS FOR COMMERCIAL CABP AND ABSSSI INDICATIONS

[***]

6. CLIN 6: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government in a VMI or deliver such inventory to the ASPR[***] in the manner described in CLIN 2.

7. CLIN 7: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government in a VMI or deliver such inventory to the ASPR[***] in the manner described in CLIN 2.

8. CLIN 8: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)

The Contractor shall store and maintain under the recommended storage conditions purchased NUZYRA® drug product inventory for the US Government in a VMI or deliver such inventory to the ASPR[***] in the manner described in CLIN 2.

9. CLIN 9: EMERGENCY DISTRIBUTION OF PROCURED ANTIBIOTIC

The Contractor is to be prepared to deploy up to [***] treatment courses of drug product from existing product in VMI to the field in the United States in the event of a national emergency or an emergency situation under an appropriate regulatory mechanism (e.g., EUA, IND or sNDA), following the agreed upon procedures between Contractor, BARDA[***]

Revised Timeline view of all active CLINs provided in the SOW (09/09/2021)

[***]

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go
CLIN 001: LATE STAGE DEVELOPMENT TO SUPPORT LICENSURE OF ANTIBIOTIC (ANTHRAX)				
	[***]			
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		[***]
[***]	[***]	[***]	[***]	[***]
CLIN 002: INITIAL PURCHASE of NUZYRA (VMI)				
	Trigger: Pre-EUA FDA Comment (WBS 2.1)			
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
CLIN 003: SUPPLEMENTAL DEVELOPMENT FOR Treatment and/or PEP for ANTHRAX				
	Trigger: Execution of Contract Modification P00003			
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
CLIN 004: BARDA SECURITY REQUIREMENTS, ON-SHORING [***]				
	[***]			
[***]	[***]	[***]	[***]	[***]
			[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
CLIN 005: POST-MARKETING STUDY COMMITMENTS / REQUIREMENTS				
	[***]			
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go
CLIN 006: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)				
	Trigger: BARDA receipt of positive top line dose response data from non-GLP dose range-finding study for treatment of inhalation anthrax in rabbits			
[***]	[***]	[***]	[***]	[***]
CLIN 007: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)				
	Trigger: BARDA receipt of positive top line dose response data from non-GLP dose range-finding studies for PEP and treatment of inhalation anthrax in NHPs and positive top line data from pivotal PEP and treatment efficacy studies of inhalation anthrax in rabbits			
[***]	[***]	[***]	[***]	[***]
CLIN 008: ADDITIONAL PROCUREMENT OF ANTIBIOTIC(S) AS FINAL DRUG PRODUCT (FDP)				
	Trigger: Paratek receives sNDA approval for treatment of inhalational anthrax			
[***]	[***]	[***]	[***]	[***]
CLIN 009: EMERGENCY DISTRIBUTION OF PROCURED ANTIBIOTIC				
	Trigger: Emergency Request from BARDA/USG			
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Evan Loh, certify that:

1. I have reviewed this Form 10-Q of Paratek Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision; to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ EVAN LOH, M.D.

Evan Loh, M.D.
Chief Executive Officer
November 8, 2021

Exhibit 31.2

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

I, Sarah Higgins, certify that:

1. I have reviewed this Form 10-Q of Paratek Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision; to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ SARAH HIGGINS

Sarah Higgins
Principal Financial Officer
November 8, 2021

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Evan Loh, M.D., Chief Executive Officer of Paratek Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021 (the "Quarterly Report"), to which this Certification is attached as Exhibit 32.1 fully complies with the requirements of Section 13(a) or Section 15(d), of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations the Company.

In Witness Whereof, the undersigned has set his hand hereto as of the 8th day of November, 2021.

/s/ EVAN LOH, M.D.

Evan Loh, M.D.
Chief Executive Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Paratek Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sarah Higgins, Principal Financial Officer of Paratek Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021 (the "Quarterly Report"), to which this Certification is attached as Exhibit 32.2 fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set her hand hereto as of the 8th day of November, 2021.

/s/ SARAH HIGGINS

Sarah Higgins
Principal Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Paratek Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.