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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2019

OR

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

For the transition period from to

Commission file number: 001-35867

CHIMERIX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**33-0903395**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2505 Meridian Parkway, Suite 100 **Durham, North Carolina**	**27713**
(Address of Principal Executive Offices)	(Zip Code)

(919) 806-1074
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company x
	Emerging growth company o

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

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

As of October 31, 2019, the number of outstanding shares of the registrant’s common stock, par value $0.001 per share, was 61,382,263.

CHIMERIX, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2019

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PART I - FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,349	$ 81,106
Short-term investments, available-for-sale	97,366	105,424
Accounts receivable	1,822	330
Prepaid expenses and other current assets	7,432	2,598
Total current assets	125,969	189,458
Property and equipment, net of accumulated depreciation	910	1,210
Operating lease right-of-use assets	836	—
Other long-term assets	36	46
Total assets	$ 127,751	$ 190,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,477	$ 4,691
Accrued liabilities	11,957	8,275
Total current liabilities	15,434	12,966
Lease-related obligations	369	144
Total liabilities	15,803	13,110
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2019 and December 31, 2018; no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 61,382,263 and 50,735,279 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	61	51
Additional paid-in capital	777,133	733,907
Accumulated other comprehensive gain (loss), net	89	(92)
Accumulated deficit	(665,335)	(556,262)
Total stockholders’ equity	111,948	177,604
Total liabilities and stockholders’ equity	$ 127,751	$ 190,714

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Contract revenue	$ 1,958	$ 369	$ 5,752	$ 2,352
Operating expenses:				
Research and development	7,453	11,892	34,795	39,963
General and administrative	4,024	5,187	18,022	18,575
Acquired in-process research and development	65,045	—	65,045	—
Total operating expenses	76,522	17,079	117,862	58,538
Loss from operations	(74,564)	(16,710)	(112,110)	(56,186)
Other (expense) income:				
Interest income and other, net	834	631	3,037	1,668
Net loss	(73,730)	(16,079)	(109,073)	(54,518)
Other comprehensive loss:				
Unrealized (loss) gain on debt investments, net	(36)	180	182	302
Comprehensive loss	$ (73,766)	$ (15,899)	$ (108,891)	$ (54,216)
Per share information:				
Net loss, basic and diluted	$ (1.26)	$ (0.33)	$ (2.04)	$ (1.14)
Weighted-average shares outstanding, basic and diluted	58,457,110	48,172,354	53,519,207	47,875,895

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

CHIMERIX, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)
(unaudited)

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2018	$ 51	$ 733,907	$ (92)	$ (556,262)	$ 177,604
Share-based compensation	—	4,073	—	—	4,073
Exercise of stock options	—	13	—	—	13
Employee stock purchase plan purchases	—	170	—	—	170
Comprehensive loss:					
Unrealized gain on investments, net	—	—	140	—	140
Net loss	—	—	—	(17,693)	(17,693)
Total comprehensive loss					(17,553)
Balance, March 31, 2019	$ 51	$ 738,163	$ 48	$ (573,955)	$ 164,307
Share-based compensation	—	2,367	—	—	2,367
Exercise of stock options	—	17	—	—	17
Employee stock purchase plan purchases	—	—	—	—	—
Comprehensive loss:					
Unrealized gain on investments, net	—	—	77	—	77
Net loss	—	—	—	(17,650)	(17,650)
Total comprehensive loss					(17,573)
Balance, June 30, 2019	$ 51	$ 740,547	$ 125	$ (591,605)	$ 149,118
Share-based compensation	—	1,529	—	—	1,529
Exercise of stock options	—	13	—	—	13
Employee stock purchase plan purchases	—	154	—	—	154
Issuance of common stock, net of issuance costs	10	34,890	—	—	34,900
Comprehensive loss:					
Unrealized gain on investments, net	—	—	(36)	—	(36)
Net loss	—	—	—	(73,730)	(73,730)
Total comprehensive loss					(73,766)
Balance, September 30, 2019	$ 61	$ 777,133	$ 89	$ (665,335)	$ 111,948

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2017	$ 47	$ 709,514	$ (963)	$ (486,788)	$ 221,810
Share-based compensation	1	3,391	—	—	3,392
Exercise of stock options	—	60	—	—	60
Employee stock purchase plan purchases	—	358	—	—	358
Comprehensive loss:					
Unrealized loss on investments, net	—	—	(103)	—	(103)
Net loss	—	—	—	(19,826)	(19,826)
Total comprehensive loss					(19,929)
Balance, March 31, 2018	$ 48	$ 713,323	$ (1,066)	$ (506,614)	$ 205,691
Share-based compensation	—	4,035	—	—	4,035
Exercise of stock options	—	55	—	—	55
Employee stock purchase plan purchases	—	—	—	—	—
Issuance of common stock, net of issuance costs	—	—	—	—	—
Comprehensive loss:					
Unrealized loss on investments, net	—	—	225	—	225
Net loss	—	—	—	(18,613)	(18,613)
Total comprehensive loss					(18,388)
Balance, June 30, 2018	$ 48	$ 717,413	$ (841)	$ (525,227)	$ 191,393
Share-based compensation	—	3,181	—	—	3,181
Exercise of stock options	—	—	—	—	—
Employee stock purchase plan purchases	—	248	—	—	248
Issuance of common stock, net of issuance costs	3	10,218	—	—	10,221
Comprehensive loss:					
Unrealized loss on investments, net	—	—	180	—	180
Net loss	—	—	—	(16,079)	(16,079)
Total comprehensive loss					(15,899)
Balance, September 30, 2018	$ 51	$ 731,060	$ (661)	$ (541,306)	$ 189,144

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (109,073)	$ (54,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	451	691
Amortization of discount/premium on investments	(1,557)	(447)
Share-based compensation	7,969	10,608
Fair value of common stock issued for license agreement	34,900	—
Unrealized loss on equity investment	—	311
(Gain)/loss on sale of investments	31	—
Lease-related amortization	(57)	(44)
Changes in operating assets and liabilities:		
Accounts receivable	(1,492)	1,350
Prepaid expenses and other assets	178	202
Accounts payable and accrued liabilities	(3,062)	(3,578)
Net cash used in operating activities	(71,712)	(45,425)
Cash flows from investing activities:		
Purchases of property and equipment	(150)	(160)
Purchases of short-term investments	(130,351)	(59,259)
Purchases of long-term investments	—	(6,031)
Proceeds from sales of short-term investments	13,112	26,000
Proceeds from maturities of short-term investments	127,000	78,500
Net cash provided by investing activities	9,611	39,050
Cash flows from financing activities:		
Proceeds from exercise of stock options	43	115
Proceeds from employee stock purchase plan	324	606
Proceeds from issuance of common stock, net of commissions	—	10,460
Payments of deferred offering costs	(23)	(363)
Net cash provided by financing activities	344	10,818
Net (decrease) increase in cash and cash equivalents	(61,757)	4,443
Cash and cash equivalents:		
Beginning of period	81,106	18,548
End of period	$ 19,349	$ 22,991

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

Note 1. The Business and Summary of Significant Accounting Policies

Description of Business

Chimerix, Inc. (the Company) is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. The Company has two clinical-stage product candidates, dociparstat sodium (DSTAT) and brincidofovir (BCV). Dociparstat sodium is a potential first-in-class glycosaminoglycan biologic derived from porcine heparin that has low anticoagulant activity but retains the ability to inhibit activities of several key proteins implicated in the retention and viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1). Mobilization of AML blasts and leukemic stem cells from the bone marrow has been associated with enhanced chemosensitivity and may be a primary mechanism accounting for the observed increases in event-free survival (EFS) and overall survival (OS) in a Phase 2 study with DSTAT versus placebo. Randomized Phase 2 data suggests that DSTAT may also accelerate platelet recovery post chemotherapy via inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy. BCV is a lipid conjugate DNA polymerase inhibitor in development as a medical countermeasure for smallpox. The Company expects to continue its evaluation of external innovation in order to license, acquire or otherwise gain access to molecules that further broaden its pipeline of investigational agents in cancer or other serious diseases.

Basis of Presentation

The accompanying unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company’s audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2018. In the opinion of the Company’s management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented have been included. Operating results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the full year, for any other interim period or for any future year.

Reclassifications

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

Fair Value of Financial Instruments

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

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

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

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

At September 30, 2019, the Company had cash equivalents including money market accounts, and at December 31, 2018, the Company had cash equivalents including money market accounts and U.S. Treasury securities, whose value is based on quoted market prices. At September 30, 2019 and December 31, 2018, the Company had short-term investments including U.S. Treasury securities, whose value is based on quoted market prices. Accordingly, these securities are classified as Level 1.

At December 31, 2018, the Company had short-term investments including stock of a U.S. corporation, ContraVir Pharmaceuticals (ContraVir). The Company's investment in ContraVir common stock was categorized as a Level 1 asset and had a value based on ContraVir's common stock value at December 31, 2018. The Company sold its investment in ContraVir in September 2019. For the three and nine months ended September 30, 2019, the Company recorded a realized loss related to the Company's investment in ContraVir common stock of approximately $3,000 and $33,000, respectively, and for the three and nine months ended September 30, 2018, the Company recorded an unrealized loss related to the Company's investment in ContraVir common stock of approximately $99,000 and $311,000, respectively, which was included in interest income and other, net in the Consolidated Statements of Operations and Comprehensive Loss.

At September 30, 2019, the Company had short-term investments including commercial paper and corporate bonds. At December 31, 2018, the Company had cash equivalents including commercial paper and corporate bonds, and short-term investments including commercial paper and corporate bonds. As quoted prices are not available for these securities, they are valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security’s credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

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

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

	Fair Value Measurements September 30, 2019			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 16,983	$ 16,983	$ —	$ —
Total cash equivalents	16,983	16,983	—	—
Short-term investments				
U.S. treasury securities	23,213	23,213	—	—
Commercial paper	34,853	—	34,853	—
Corporate bonds	39,300	—	39,300	—
Total short-term investments	97,366	23,213	74,153	—
Total assets	$ 114,349	$ 40,196	$ 74,153	$ —

	Fair Value Measurements December 31, 2018			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 30,726	$ 30,726	$ —	$ —
U.S. treasury securities	11,482	11,482	—	—
Commercial paper	29,677	—	29,677	—
Corporate bonds	4,008	—	4,008	—
Total cash equivalents	75,893	42,208	33,685	—
Short-term investments				
U.S. treasury securities	12,589	12,589	—	—
Common stock of U.S. corporation	38	38	—	—
Commercial paper	60,114	—	60,114	—
Corporate bonds	32,683	—	32,683	—
Total short-term investments	105,424	12,627	92,797	—
Total assets	$ 181,317	$ 54,835	$ 126,482	$ —

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued research and development expenses	$ 2,683	$ 4,525
Accrued compensation	3,139	2,469
Other accrued liabilities	1,054	1,168
Deferred revenue	5,081	113
Total accrued liabilities	$ 11,957	$ 8,275

Revenue Recognition

Policy

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

Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, the Company entered into a contract with BARDA for the advanced development of BCV as a medical countermeasure in the event of a smallpox release. Under the contract, the Company may receive up to $75.8 million in expense reimbursement and $5.3 million in fees over the performance of 1 base segment and 4 option segments. Exercise of each option segment is solely at the discretion of BARDA. Currently, option segments 1 through 3 have been exercised. The Company assessed the services in accordance with the authoritative guidance and concluded that there is a potential of 5 separate contracts (1 base segment and 4 option segments) within this agreement, each of which has a single performance obligation. The transaction price for each segment, based on the transaction price as defined in each segment contract, is allocated to the single performance obligation for each contract. The transaction price is recognized over time by measuring the progress toward complete satisfaction of the performance obligation. The progress toward complete satisfaction is estimated based on the costs incurred to date relative to the total estimated costs per the terms of each contract. The Company typically invoices BARDA monthly as costs are incurred. The base segment and first option segment were completed prior to adoption of ASC 606. The Company is currently performing under the second and third option segments of the contract during which the Company may receive up to a total of $23.9 million and $14.1 million in expense reimbursement and fees, respectively. The second option and third option segments are scheduled to end on May 31, 2020.

SymBio Pharmaceuticals

On September 30, 2019, the Company entered into a license agreement with SymBio Pharmaceuticals Limited (SymBio) for the exclusive worldwide rights to develop, manufacture and commercialize BCV for all human indications, excluding the prevention and treatment of orthopoxviruses, including smallpox. The Company assessed the agreement in accordance with the authoritative guidance and concluded that the SymBio contract includes multiple performance obligations, which have not been fulfilled as of September 30, 2019. The SymBio contract has one fixed transaction amount of a $5.0 million upfront payment due to the Company on or before October 22, 2019 and several variable transaction amounts, up to $180 million, due to the Company at certain regulatory and commercial milestones, along with low double-digit royalties, due to the Company on annual net sales. All variable transaction amounts are fully constrained, therefore the allocated transaction price is $5.0 million. The majority of the transaction price of the contract has been allocated to the combined performance obligation of the granting of the license to BCV and associated technology transfer and will be recognized when the technology transfer is complete, which is expected to occur in the fourth quarter of 2019. The revenue from regulatory and commercial milestones and royalties from net sales will be recognized upon occurrence of the triggering events or when those transaction amounts are no longer fully constrained. At September 30, 2019, the Company recorded a $5.0 million receivable due from SymBio in prepaid expenses and other current assets and $5.0 million of deferred revenue in accrued liabilities.

Research and Development Prepaids and Accruals

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with its research and development efforts. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts.

The Company's objective is to reflect the appropriate research and development expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of its research and development efforts. The Company determines prepaid and accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of clinical trials, or other services completed. The Company adjusts its rate of research and development expense recognition if actual results differ from its estimates. The Company makes estimates of its prepaid and accrued expenses as of each balance sheet date in its financial

statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through September 30, 2019, there had been no material adjustments to the Company's prior period estimates of prepaid and accruals for research and development expenses. The Company's research and development prepaids and accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Basic and Diluted Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of non-vested restricted stock, stock options, and employee stock purchase plan purchase rights. Diluted net loss per share of common stock is computed by dividing net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of warrants to purchase common stock, non-vested restricted stock, stock options, and employee stock purchase plan purchase rights outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted loss per share of common stock for the three and nine months ended September 30, 2019 and 2018.

Impact of Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach on expected losses to estimate credit losses on certain financial instruments, including trade receivables and available-for-sale debt securities. The new guidance will be effective for the Company beginning in the first quarter of 2020, with early adoption permitted. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements.

Impact of Recently Adopted Accounting Standards

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, "Leases (Topic 842)", which has been amended through subsequent ASUs, and which increases transparency and comparability among companies accounting for lease transactions. The most significant change of this update requires the recognition of lease assets and liabilities on the balance sheet for lessees for operating lease arrangements with lease terms greater than 12 months. This ASU is effective for financial statements issued for annual periods and interim periods within those annual periods, beginning after December 15, 2018. The Company adopted this standard effective January 1, 2019 using the alternative modified retrospective adoption method allowed by ASU 2018-11. The Company elected to use the package of three practical expedients which allows the Company not to reassess whether contracts are or contain leases, lease classification, and whether initial direct costs qualify for capitalization. The Company has completed its assessment of the impact of the standard and determined that the only material leases that the Company holds are real estate operating leases. Upon adoption of the standard, the Company recorded a right of use asset of $1.4 million and lease liability of $1.6 million on its consolidated balance sheets with no adjustment to beginning retained earnings in the period of adoption.

Note 2. Investments

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

	September 30, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 39,249	$ 54	$ (3)	$ 39,300
U.S. treasury securities	23,191	22	—	23,213
Commercial paper	34,837	18	(2)	34,853
Total investments	$ 97,277	$ 94	$ (5)	$ 97,366

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ 32,724	$ —	$ (41)	$ 32,683
Commercial paper	60,159	—	(45)	60,114
U.S. treasury securities	12,592	—	(3)	12,589
Total investments	$ 105,475	$ —	$ (89)	$ 105,386

The following tables summarize the Company's debt investments with unrealized losses, aggregated by investment type and the length of time that individual investments have been in a continuous unrealized loss position (in thousands, except number of securities):

	September 30, 2019					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 2,493	$ (3)	$ —	$ —	$ 2,493	$ (3)
Commercial paper	$ 4,946	$ (2)	$ —	$ —	$ 4,946	$ (2)
Total	$ 7,439	$ (5)	$ —	$ —	$ 7,439	$ (5)
Number of securities with unrealized losses		3		—		3

	December 31, 2018					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 32,683	$ (41)	$ —	$ —	$ 32,683	$ (41)
Commercial paper	60,114	(45)	—	—	60,114	(45)
U.S. treasury securities	12,589	(3)	—	—	12,589	(3)
Total	$ 105,386	$ (89)	$ —	$ —	$ 105,386	$ (89)
Number of securities with unrealized losses		36		—		36

The Company periodically reviews available-for-sale debt investments for other-than-temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company evaluates, among other things, the duration and extent to which the fair value of a security is less than its cost; the financial condition of the issuer and any changes thereto; and the Company's intent to sell, or whether it will more likely than not be required to sell, the security before recovery of its cost basis. At September 30, 2019, the Company did not intend to sell, and

was not more likely than not to be required to sell, the available-for-sale debt investments in an unrealized loss position before recovery of the cost basis of the securities, which may be at maturity. There were no such declines in value for the three and nine months ended September 30, 2019 and 2018. Unrealized gains and losses on debt investments are recorded to unrealized (loss) gain on investments, net in the Consolidated Statements of Operations and Comprehensive Loss. The Company recognizes interest income on an accrual basis in interest income in the Consolidated Statements of Operations and Comprehensive Loss.

The following table summarizes the scheduled maturity for the Company's debt investments at September 30, 2019 (in thousands):

Maturing in one year or less	$	97,366
Maturing after one year through two years		—
Total debt investments	$	97,366

Note 3. Commitments and Contingencies

Leases

The Company leases its facilities under long-term operating leases that expire at various dates through 2021. The Company generally has options to renew lease terms on its facilities, which may be exercised at the Company's sole discretion. In addition, certain lease arrangements may be terminated prior to their original expiration date at the Company's discretion. The Company evaluates renewal and termination options at the lease commencement date to determine if it is reasonably certain to exercise the option and has concluded on all operating leases that it is not reasonably certain that any options will be exercised. The weighted-average remaining lease term for the Company's operating leases as of September 30, 2019 was 1.52 years.

Expense related to leases is recorded on a straight-line basis over the lease term. Lease expense under operating leases, including common area maintenance fees, totaled approximately $187,000 and $180,000, respectively, for the three months ended September 30, 2019 and 2018, and $563,000 and $531,000 for the nine months ended September 30, 2019 and 2018, respectively.

The discount rate implicit within the Company's leases is generally not determinable and therefore the Company determines the discount rate based on its incremental borrowing rate based on the information available at commencement date. As of September 30, 2019, the operating lease liabilities reflect a weighted-average discount rate of 13.06%.

The following table sets forth the operating lease right-of-use assets and liabilities as of September 30, 2019 (in thousands):

Assets		
Operating Lease Right-of-Use Assets	$	836
Liabilities		
Operating Lease Short-term Liabilities (recorded within Accrued liabilities)	$	630
Operating Lease Long-term Liabilities (recorded within Lease-related obligations)		352
Total Operating Lease Liabilities	$	982

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

Years Ending December 31,		**As of September 30, 2019**
2019	$	176
2020		719
2021		182
Total future minimum rental payments	$	1,077
Less amount of lease payments representing interest		95
Total present value of lease payments	$	982

As of December 31, 2018, future minimum payments under operating leases under ASC 840 were as follows (in thousands):

Years Ending December 31,	As of December 31, 2018
2019	$ 786
2020	797
2021	235
Total future minimum rental payments	$ 1,818

For the three months ended September 30, 2019 and 2018, the Company made lease payments of approximately $188,000 and $189,000, respectively, and for the nine months ended September 30, 2019 and 2018, the Company made lease payments of approximately $574,000 and $559,000, respectively, which are included in operating cash flows.

Sublease

The Company subleases 3,537 square feet of its office space under a non-cancelable operating lease that expires in February 2021. For the three and nine months ended September 30, 2019, the Company recognized approximately $18,000 and $53,000 of income in Interest income and other, net on the Consolidated Statement of Operations and Comprehensive Loss. For the three and nine months ended September 30, 2018, the Company recognized approximately $18,000 and $53,000 of a reduction of rent expense in operating expenses on the Consolidated Statement of Operations and Comprehensive Loss. Total future minimum rentals under the non-cancelable operating sublease are presented below (in thousands):

Years Ending December 31,	As of September 30, 2019
2019	$ 19
2020	81
2021	14
Total future minimum sublease rentals	$ 114

Significance of Revenue Source

The Company is the recipient of federal research contract funds from BARDA, the sole source of the Company's contract revenue. Periodic audits are required under the Company’s BARDA agreement and certain costs may be questioned as appropriate under the BARDA agreement. Management believes that such amounts in the current year, if any, are not significant. Accordingly, no provision for refundable amounts under the BARDA agreement had been made as of September 30, 2019 and December 31, 2018.

Note 4. Equity Transactions and Share-based Compensation

Stock Options

The Company maintains a 2013 Equity Incentive Plan (the 2013 Plan), which provides for the grant of incentive stock options (ISOs), non-statutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company and its affiliates. Additionally, the 2013 Plan provides for the grant of performance cash awards. The number of shares of common stock reserved for future issuance automatically increases on January 1 of each calendar year by 4% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company’s board of directors. On January 1, 2019, the common stock reserved for issuance under the 2013 Plan was automatically increased by 2.0 million shares. As of September 30, 2019, there was a total of 1.9 million shares reserved for future issuance under the 2013 Plan. The Company issued approximately 5,000 and 19,000 shares of common stock pursuant to the exercise of stock options during the three and nine months ended September 30, 2019, respectively.

Employee Stock Purchase Plan

The Company maintains a 2013 Employee Stock Purchase Plan (ESPP), which provides for the issuance of shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its designated affiliates. The Company has reserved a total of 3.1 million shares of common stock to be purchased under the ESPP, of which 2.3 million shares remained available for purchase as of September 30, 2019. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year, from January 1, 2014 through January 1, 2023 by the lesser of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 422,535 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). On January 1, 2019, the common stock reserved for issuance under the ESPP was automatically increased by an additional 422,535 shares.

The ESPP provides for an automatic reset feature to start participants on a new twenty-four month participation period in the event that the common stock market value on a purchase date is less than the common stock value on the first day of the twenty-four month offering period. Eligible employees may authorize an amount up to 15% of their salary to purchase common stock at the lower of a 15% discount to the beginning price of their offering period or a 15% discount to the ending price of each six-month purchase interval. The Company issued 96,000 shares of common stock pursuant to the ESPP during the three months ended September 30, 2019. The Company issued approximately 209,000 shares of common stock pursuant to the ESPP during the nine months ended September 30, 2019. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option and were determined using a Black-Scholes option pricing model.

Restricted Stock Units

The Company has issued RSUs to certain employees which vest based on service criteria. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The grant date fair value for RSUs is based upon the market price of the Company's common stock on the date of the grant. The fair value is then amortized to compensation expense over the requisite service period or vesting term. The Company issued approximately 50,000 and 419,000 shares of common stock pursuant to the vesting of RSUs during the three and nine months ended September 30, 2019, respectively.

Stock-based Compensation

For awards with only service conditions and graded-vesting features, the Company recognizes compensation expense on a straight-line basis over the requisite service period. Total share-based compensation expense recognized related to stock options, the ESPP and RSUs was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development expense	$ 901	$ 1,370	$ 3,170	$ 4,226
General and administrative expense	628	1,811	4,799	6,382
Total share-based compensation expense	$ 1,529	$ 3,181	$ 7,969	$ 10,608

On February 5, 2019, Dr. M. Michelle Berrey, the Company's then President and Chief Executive Officer, resigned. The Company entered into a severance agreement with Dr. Berrey that provides for severance benefits to her in connection with her resignation. Among other benefits, Dr. Berrey received accelerated vesting of her outstanding stock options and RSUs as if she had continued service for an additional 15 month period. In addition, Dr. Berrey's vested options were modified to extend her exercise period to May 5, 2020. The Company recorded a charge of $1.8 million to compensation expense on the date of her resignation related to the acceleration of vesting and the modifications of her outstanding stock options and RSUs.

In April 2019, the Company granted stock options covering a total of 1,750,000 shares in connection with the hiring of its Chief Executive Officer and Chief Business Officer. These grants were non-qualified stock options, have a 10-year term and will vest over four years, with one-fourth vesting on the one-year anniversary of the grant date and remaining three-fourths vesting over the following three years in equal monthly installments. These stock options are subject to the terms of the Company's 2013 Equity Incentive Plan, but were granted outside of the 2013 Equity Incentive Plan, as they constituted inducement grants in accordance with Nasdaq Stock Market rules.

In May 2019, related to the Company's reduction in workforce further discussed in Note 7, certain outstanding stock option and RSU grants received accelerated vesting as if the service period of the terminated employee continued for an additional 12 month

period. In addition, certain vested options were modified to extend their exercise period for 12 months. The Company recorded a charge of $0.7 million to compensation expense on the date of the reduction in workforce related to the acceleration of vesting and the modifications of the outstanding stock options and RSUs.

Note 5. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2019 as the Company incurred losses for the nine month period ended September 30, 2019, and is forecasting an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2019. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method in accordance with FASB ASC 740.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company cannot currently support that realization of its deferred tax assets is more likely than not. However, the Company feels its deferred tax assets may be used upon the Company becoming profitable.

At September 30, 2019, the Company had no unrecognized tax benefits that would reduce the Company’s effective tax rate if recognized.

Note 6. Significant Agreements

The Regents of the University of California

In May 2002, the Company entered into a license agreement with The Regents of the University of California (UC) under which the Company obtained an exclusive, worldwide license to UC’s patent rights in certain inventions (the UC Patent Rights) related to lipid-conjugated antiviral compounds and their use, including certain patents relating to BCV. The license agreement was terminated effective September 29, 2019. The termination of the license to the UC Patent Rights does not affect the Chimerix solely-owned patents covering BCV composition of matter that currently are set to expire in 2034.

Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, the Company entered into a contract with BARDA for the advanced development of BCV as a medical countermeasure in the event of a smallpox release. Under the contract, BARDA will reimburse the Company, plus pay a fixed fee, for the research and development of BCV as a broad-spectrum therapeutic antiviral for the treatment of smallpox infections. The contract consists of an initial performance period, referred to as the base performance segment, plus up to four extension periods, referred to as option segments, each of which may be exercised at BARDA’s sole discretion. The Company must complete the agreed upon milestones and deliverables in each discrete work segment before the next option segment is eligible to be exercised. Under the contract as currently in effect, the Company may receive up to $75.8 million in expense reimbursement and $5.3 million in fees.

The Company is currently performing under the second and third option segments of the contract during which the Company may receive up to a total of $23.9 million and $14.1 million in expense reimbursement and fees, respectively. The second and third option segments are scheduled to end on May 31, 2020. Of the $75.8 million in expense reimbursement and $5.3 million in fees that the Company may receive, approximately $74.3 million in expense reimbursement and fees has been funded. As of September 30, 2019, of the total funding the Company had invoiced an aggregate of $68.3 million with respect to the base performance segment and the first three option segments. For the three months ended September 30, 2019 and 2018, the Company recognized revenue under this contract of $2.0 million and $0.4 million, respectively, and for the nine months ended September 30, 2019 and 2018, the Company recognized revenue under this contract of $5.8 million and $2.4 million, respectively.

License and Development Agreement with Cantex Pharmaceuticals, Inc.

On July 26, 2019, the Company entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which the Company acquired exclusive worldwide rights to develop and commercialize, for any and all uses, a glycosaminoglycan biologic known as DSTAT, which is currently being studied for the treatment of acute myeloid leukemia. Under the terms of the license agreement, the Company will be responsible for, and bear the future costs of, worldwide development and commercialization of DSTAT. In connection with the transaction, Cantex assigned to the Company all of its rights under its DSTAT

supply agreements, including its bulk API agreement with Scientific Protein Laboratories LLC (SPL), pursuant to which SPL will exclusively produce DSTAT for the Company through October 2030.

In consideration for the license rights, the Company made an upfront cash payment of $30.0 million to Cantex and issued to Cantex 10.0 million shares of its common stock. For the three and nine months ended September 30, 2019, the Company recognized $65.0 million of acquired in-process research and development expenses for the $30.0 million upfront cash payment, the fair value of the 10.0 million shares of common stock issued to Cantex and $0.1 million of transaction costs. The license agreement obligates the Company to pay Cantex regulatory milestone payments of up to $202.5 million upon receipt of product approvals in the United States, the European Union and Japan, and sales milestone payments of up to $385.0 million upon achievement of specified net sales levels. The Company also agreed to pay Cantex tiered royalties based on percentages of net sales beginning at 10% and not to exceed the high-teens.

SymBio Pharmaceuticals

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

In exchange for the license to BCV rights, the Company is due an upfront payment of $5.0 million on or before October 22, 2019. In addition, the Company is eligible to receive up to $180.0 million in clinical, regulatory and commercial milestones worldwide, as well as low double-digit royalties and additional milestones based on commercial sales. At September 30, 2019, the Company had a $5.0 million receivable due from SymBio recorded in Prepaid expenses and other current assets and a $5.0 million deferred revenue balance recorded in Accrued liabilities.

University of Michigan

In 2006, the Company entered into a license agreement with The Regents of the University of Michigan (UM) under which the Company obtained an exclusive, worldwide license to UM’s patent rights in certain inventions (UM Patent Rights) related to certain compounds originally synthesized at UM. Under the license agreement, the Company is permitted to research, develop, manufacture and commercialize products utilizing the UM Patent Rights, and to sublicense such rights subject to certain sublicensing fees and royalty payments.

In consideration for the rights granted to the Company, under the license agreement as amended in December 2016, the Company paid UM $50,000 in fees in 2016 and in January 2017 issued UM an aggregate of 33,058 shares of its common stock. In connection with the Company's commercialization or sublicensing of certain products covered by the license agreement, including CMX521, the Company could be required to pay royalties on net sales of such products ranging from 0.25% to 2%. Beginning in 2024, the Company is also subject to certain minimum annual royalty payments.

The UM license agreement requires that the Company use commercially reasonable efforts to develop and make commercially available licensed products as soon as practicable. Specifically, the Company has agreed to make the first commercial sale of a licensed product by June of 2026. UM may terminate the license agreement if the Company materially breaches the license agreement. The Company is currently in compliance with its milestone requirements.

Note 7. Restructuring Costs

In May 2019, the Company made the decision to discontinue the development of oral and IV BCV development programs for the treatment of Adenovirus (AdV) in stem-cell transplant (HCT) patients. The Company's development efforts with respect to BCV are now focused on the treatment of smallpox. As a result, the Company restructured its operations, which included a reduction in workforce of 43 full-time employees and the accrual of expenses to close-out the clinical trials for the oral and IV development programs of BCV in AdV (study 210, study 211, AdAPT) and other supportive BCV development programs. The Company recorded charges for one-time employee termination benefits of $3.3 million, contract close-out costs of $2.7 million, and other BCV development costs of $0.3 million during the nine months ended September 30, 2019. The $2.7 million of contract close-out costs were recorded through an increase in liabilities of $2.1 million with the remainder recognized through the expensing of prepaid balances. As of September 30, 2019, the Company had a clinical trial accrual balance related to the AdAPT, 210 and 211 trial terminations of $0.4 million and other development costs accrual balance of $0.1 million, which are

expected to be substantially paid by the end of the year. As of September 30, 2019, the Company had a severance accrual balance of $0.5 million, which is expected to be fully paid by June 2020.

The following table summarizes the restructuring charges (in thousands) recorded for the nine months ended September 30, 2019:

	Employee Termination Benefits	Clinical Trial Close-out Costs	Other Development Costs	Total
Research and development	1,426	2,680	316	4,422
General and administrative	1,909	—	—	1.909
Total restructuring expenses	3,335	2,680	316	6,331

The following table sets forth the accrual activity for employee termination benefits and contract close-out costs (in thousands) for the three and nine months ended September 30, 2019. No additional charges are expected to be incurred.

	Employee Termination Benefits	Clinical Trial Close-out Costs	Other Development Costs	Total
Balance at June 30, 2019	1,784	2,062	315	4,161
Revised estimates	—	36	1	37
Payments	(1,294)	(1,664)	(169)	(3,127)
Balance at September 30, 2019	490	434	147	1,071

	Employee Termination Benefits	Clinical Trial Close-out Costs	Other Development Costs	Total
Balance at January 1, 2019	—	—	—	—
Accruals	3,335	2,131	315	5,781
Revised estimates	—	36	1	37
Payments	(2,845)	(1,733)	(169)	(4,747)
Balance at September 30, 2019	490	434	147	1,071

In addition to the approximately $37,000 of revised estimates to accrued liabilities, the Company revised estimates of prepaid clinical trial balances included in prepaid expenses and other current assets, which resulted in the reduction of clinical trial close-out costs by approximately $193,000 for the three and nine months ended September 30, 2019.

Note 8. Subsequent Events

The Company has evaluated subsequent events through the issuance date of these financial statements to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2019, and events which occurred subsequently but were not recognized in the financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (SEC) on March 5, 2019. Past operating results are not necessarily indicative of results that may occur in future periods.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item IA, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

OVERVIEW

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. The two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

Dociparstat sodium is a potential first-in-class glycosaminoglycan biologic derived from porcine heparin that has low anticoagulant activity but retains the ability to inhibit activities of several key proteins implicated in the retention and viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, p-selectin, HMGB1, galectin-3). Mobilization of AML blasts and leukemic stem cells from the bone marrow has been associated with enhanced chemosensitivity and may be a primary mechanism accounting for the observed increases in EFS and OS in Phase 2 with DSTAT versus placebo. Randomized Phase 2 data suggests that DSTAT may also accelerate platelet recovery post chemotherapy via inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy. BCV is a lipid conjugate DNA polymerase inhibitor in development as a medical countermeasure for smallpox. We expect to continue our evaluation of external innovation in order to license, acquire or otherwise gain access to molecules that further broaden our pipeline of investigational agents in cancer or other serious diseases.

Recent Developments

Dociparstat for First-Line Acute Myeloid Leukemia (AML)

In July 2019 we entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which we acquired exclusive worldwide rights to develop and commercialize DSTAT, for any and all uses. DSTAT is a potential first-in-class glycosaminoglycan biologic derived from porcine heparin that has low anticoagulant activity, but retains the ability to inhibit activities of several key proteins implicated in the retention and viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1). Under the terms of the license agreement, we will be responsible for, and bear the future costs of, worldwide development and commercialization of DSTAT.

In consideration for the license rights, we made an upfront cash payment of $30.0 million and issued 10,000,000 shares of our common stock to Cantex. The license agreement obligates us to pay Cantex regulatory milestone payments of up to $202.5 million upon receipt of product approvals in the United States, the European Union and Japan, and sales milestone payments of up to $385.0 million upon achievement of specified net sales levels. We also agreed to pay Cantex tiered royalties based on percentages of net sales beginning at 10% and not to exceed the high-teens.

DSTAT has received Fast Track and Orphan Drug Designations from the U.S. Food and Drug Administration for the treatment of AML.

In October 2019, we presented final results from the recently completed Phase 2b, randomized control trial of DSTAT in AML. The study evaluated DSTAT (4 mg/kg intravenous (IV) bolus followed by either 0.125 or 0.25 mg/kg/hr continuous IV infusion for 7 days) in combination with standard 7+3 chemotherapy versus chemotherapy alone in 75 subjects greater than 60 years of age with newly diagnosed AML. An analysis of the intent-to-treat (ITT) population in this study indicated that patients receiving DSTAT 0.25 mg/kg/hr exhibited improved hazard ratios for event-free survival (EFS, 0.67), overall survival (OS, 0.68) and relapse free-survival (RFS, 0.45) when compared to control patients. Complete response rates (CR/CRi) were similar between the arms. An analysis of subjects meeting the likely target inclusion criteria for the Phase 3 study, which excludes patients with feasible cytogenetics or secondary AML, indicated improved hazard ratios for DSTAT 0.25 mg/kg/hr versus control for EFS (0.58,Fig. 1), OS (0.51,Fig. 2), and RFS (0.39,Fig. 3).

Fig. 1

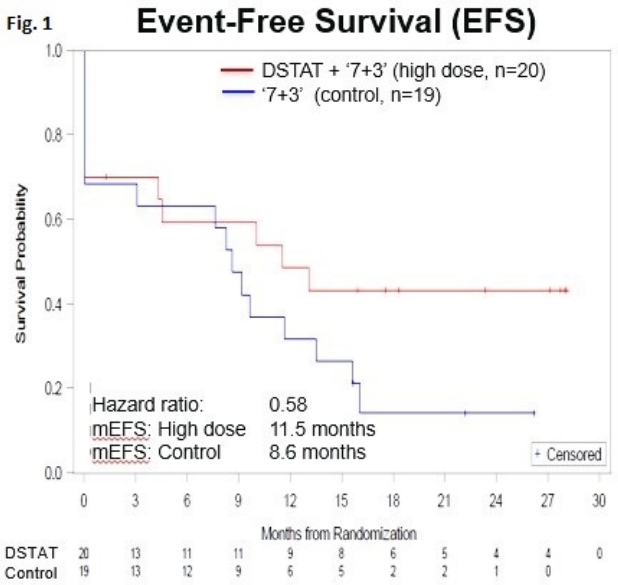
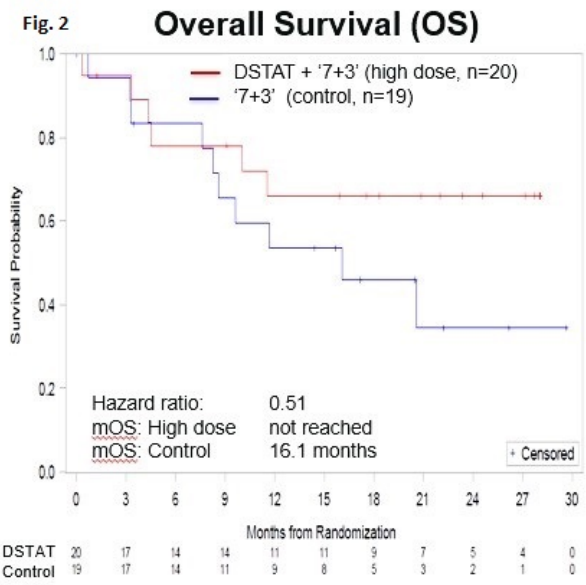
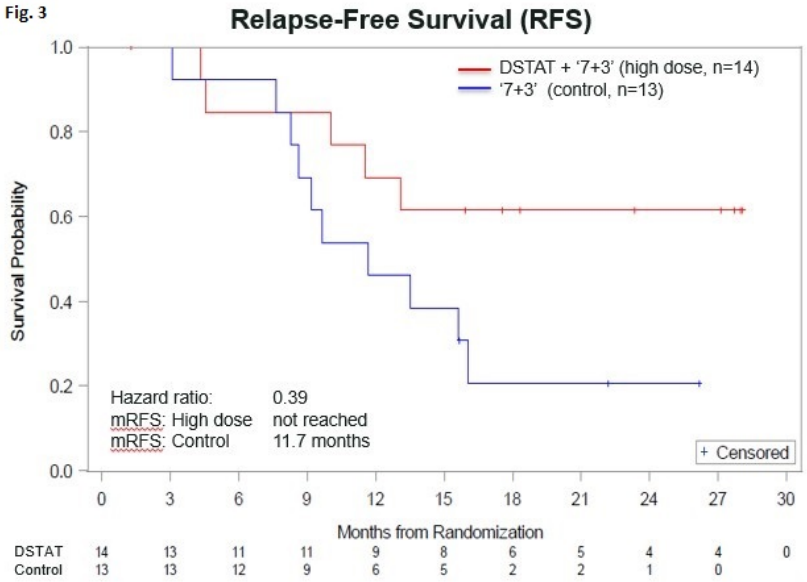


Fig. 2



Response Summary	**% CR/CRi[(a-c)]**
High Dose Arm	70% (14/20)
Control Arm	68% (13/19)
Reported Rates in the Literature ~ 50%	

(a) Complete Response (CR) or Complete Response without complete hematologic recovery (CRi)
(b) CR/CRi was with bone marrow (BM) biopsy at day 14 or beyond and where less than 5% blasts were present
(c) Responses and Kaplan-Meier curves do not include sub therapeutic low-dose arm



(a) Relapse-Free Survival = survival without relapse following induction success (CR/CRi)
(b) Responses and Kaplan-Meier curves do not include subtherapeutic low-dose arm

Combination treatment with 7+3 chemotherapy and DSTAT did not show significant added toxicity at the 0.125 or 0.25 mg/kg/hr doses. The most common serious adverse event in the DSTAT arm was febrile neutropenia. DSTAT also showed signs of accelerating platelet and neutrophil recovery following chemotherapy, consistent with the reported DSTAT inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy.

We plan to initiate a Phase 3 clinical trial of DSTAT for the treatment of AML in mid-2020, subject to an end-of-phase 2 meeting with the U.S. FDA expected to occur in early 2020.

Oral Brincidofovir for the Treatment of Smallpox

We intend to conduct a pre-NDA meeting with the FDA in the first quarter of 2020 and submit marketing applications for BCV in mid-2020, contingent upon final audited results of the animal efficacy studies and the finalization of animal PK analysis necessary to bridge to a recommended human dose. Earlier this year, we reported statistically significant and clinically meaningful reduction in mortality from GLP mousepox and rabbitpox studies. Data from these studies are intended to address the requirement under the FDA's Animal Efficacy Rule for two different animal models of efficacy.

Data from these studies are intended to address the requirement under the FDA's Animal Efficacy Rule for two different animal models of efficacy. Further confirmatory analyses (e.g. secondary endpoints) of these studies are currently underway.

License and Development Agreement with SymBio Pharmaceuticals, Ltd.

On September 30, 2019, we entered into a license agreement with SymBio Pharmaceuticals, Ltd. (SymBio) for the development and commercialization of BCV for all human indications with the exception of orthopoxviruses, including smallpox. In consideration for the license, we are due an upfront payment of $5.0 million with the potential for future clinical, regulatory and commercial milestones up to $180.0 million. In addition, we are eligible to receive low double-digit royalties on net sales of BCV worldwide.

Business Development Review

In addition to our recently completed transaction with Cantex, management is continuing to conduct a review and assessment of potential transaction opportunities with the goal of building our product candidate pipeline, including, but not limited to, licensing, merger or acquisition transactions, issuing or transferring shares of common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that this review will result in the identification or consummation of any additional transaction.

FINANCIAL OVERVIEW

Revenues

To date, we have not generated any revenue from product sales. All of our revenue to date has been derived from a government grant and contract and the receipt of up-front proceeds under our collaboration and license agreements.

In February 2011, we entered into a contract with BARDA, a U.S. governmental agency that supports the advanced research and development, manufacturing, acquisition, and stockpiling of medical countermeasures. The contract originally consisted of an initial performance period, referred to as the base performance segment, which ended on May 31, 2013, plus up to four extension periods, referred to as option segments. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at our discretion. The contract is a cost plus fixed fee development contract. Under the contract as currently in effect, we may cumulatively receive up to $75.8 million in expense reimbursement and $5.3 million in fees if the remaining option segment is exercised. We are currently performing under the second and third option segments of the contract during which we may receive up to a total of $23.9 million and $14.1 million in expense reimbursement and fees, respectively. The second and third option segments are scheduled to end on May 31, 2020. Of the $75.8 million expense reimbursement and $5.3 million in fees that we may receive, approximately $74.3 million in expense reimbursement and fees has been funded. As of September 30, 2019, of the total funding the Company had invoiced an aggregate of $68.3 million with respect to the base performance segment and the first three option segments. Under the BARDA contract, we recognized revenue of $2.0 million and $0.4 million during the three months ended September 30, 2019 and 2018, respectively, and we recognized revenue of $5.8 million and $2.4 million during the nine months ended September 30, 2019 and 2018, respectively.

In September 2019, we entered into a license agreement with SymBio for worldwide rights to develop, manufacture and commercialize BCV in all human indications, excluding the use for treatment of orthopoxviruses, including smallpox. Under the contract, we received a $5.0 million upfront payment in October 2019 and could receive up to an additional $180.0 million in potential regulatory and commercial milestones. As of September 30, 2019, we had not recognized revenue under this agreement. The majority of the upfront payment will be recognized when the technology transfer is complete, which is expected to occur in the fourth quarter of 2019. The revenue from regulatory and commercial milestones and royalties from net sales will be recognized upon occurrence of the triggering events.

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

Research and Development Expenses

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

- fees paid to consultants and contract research organizations (CROs), including in connection with preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- salaries and related overhead expenses, which include stock option, restricted stock units and employee stock purchase program compensation and benefits, for personnel in research and development functions;
- payments to third-party manufacturers, which produce, test and package drug substance and drug product (including continued testing of process validation and stability);
- costs related to legal and compliance with regulatory requirements; and
- license fees for and milestone payments related to licensed products and technologies.

The table below summarizes our research and development expenses for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Direct research and development expenses	$ 3,730	$ 6,290	$ 18,680	$ 21,718
Research and development personnel costs - excluding stock-based compensation	2,025	3,197	10,283	9,971
Research and development personnel costs - stock-based compensation	901	1,370	3,171	4,226
Indirect research and development expenses	797	1,035	2,661	4,048
Total research and development expenses	$ 7,453	$ 11,892	$ 34,795	$ 39,963

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

Dociparstat sodium (DSTAT)

In July of 2019, we acquired DSTAT from Cantex Pharmaceuticals. In connection with the transaction we recorded a total of $65.0 million in expense. This is comprised of a $30.0 million upfront payment, $34.9 million in stock-based compensation and $0.1 million in transaction costs. To date, we have incurred minimal research and development costs in connection with the program. As we continue to focus on the development of DSTAT for first-line treatment of AML patients, we expect research and development expense to increase. We plan to initiate a Phase 3 trial in AML in mid-2020.

Brincidofovir

We are developing BCV for the treatment of smallpox. Under our cost plus fixed fee BARDA contract we incurred expense in connection with the development of orthopoxvirus animal models, the demonstration of efficacy and pharmacokinetics of BCV in the animal models, the conduct of an open label clinical safety study for subjects with DNA viral infections, and the manufacture and process validation of bulk drug substance and BCV 100 mg tablets.

Historically, the majority of our research and development efforts have been focused on completing our Phase 3 trial of BCV for prevention of CMV in HCT recipients (SUPPRESS), our trial of BCV as a treatment for AdV (AdVise), the AdAPT study in pediatric HCT recipients and our other clinical and preclinical studies and other work needed to provide sufficient data supporting the safety, tolerability and efficacy of BCV for approval in the United States and equivalent health authority approval outside the United States. In May 2019, we discontinued both the oral and IV development programs of BCV in AdV and the associated clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, marketing, investor relations, information technology, legal, human resources and administrative support functions, including share-based compensation expenses and benefits. Other significant general and administrative expenses include costs related to commercial readiness efforts, accounting and legal services, costs of various consultants, director and officer liability insurance, occupancy costs and information systems.

Interest Income and Other, Net

Interest income and other, net consists primarily of interest earned on our cash, cash equivalents, short-term investments and long-term investments and decreases in fair value as well as realized losses of our investment in ContraVir Pharmaceuticals common stock.

Share-based Compensation

The Financial Accounting Standards Board authoritative guidance requires that share-based payment transactions with employees

be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. Total consolidated share-based compensation expense of $1.5 million and $3.2 million was recognized in the three months ended September 30, 2019 and 2018, respectively, and $8.0 million and $10.6 million was recognized in the nine months ended September 30, 2019 and 2018, respectively. The share-based compensation expense recognized included expense for stock options, RSUs and employee stock purchase plan purchase rights.

We estimate the fair value of our share-based awards to employees and directors using the Black-Scholes pricing model. This estimate is affected by our stock price as well as assumptions including the expected volatility, expected term, risk-free interest rate, expected dividend yield, expected rate of forfeiture and the fair value of the underlying common stock on the date of grant.

For performance-based RSUs, we begin to recognize the expense when it is deemed probable that the performance-based goal will be achieved. We evaluate the probability of achieving performance-based goals on a quarterly basis.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. In addition, our reported financial condition and results of operations could vary if new accounting standards are enacted that are applicable to our business.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in Note 1 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 5, 2019. There have been no material changes during the nine months ended September 30, 2019 to our critical accounting policies, significant judgments and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Acquired In-Process Research and Development (IPR&D) Expense

We have acquired and may continue to acquire the rights to develop and commercialize new drug candidates. In accordance with Accounting Standards Codification, or ASC, Subtopic 730-10-25, Accounting for Research and Development Costs, the up-front payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired IPR&D in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Upon obtaining regulatory approval for marketing, any subsequent milestone payments may be capitalized and amortized over the life of the asset.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2019 and September 30, 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and September 30, 2018, together with the changes in those items (in thousands, except percentages):

	Three Months Ended September 30,		Dollar Change	% Change
	2019	2018	Increase/(Decrease)	
Contract revenue	$ 1,958	$ 369	$ 1,589	430.6 %
Operating expenses:				
Research and development	7,453	11,892	(4,439)	(37.3)%
General and administrative	4,024	5,187	(1,163)	(22.4)%
Acquired in-process research and development	65,045	—	65,045	*
Total operating expenses	76,522	17,079	59,443	348.0 %
Loss from operations	(74,564)	(16,710)	(57,854)	346.2 %
Other (expense) income:				
Interest income and other, net	834	631	203	32.2 %
Net loss	$ (73,730)	$ (16,079)	$ (57,651)	358.5 %

* Not meaningful or not calculable

Contract Revenue

For the three months ended September 30, 2019, total contract revenue increased to $2.0 million compared to $0.4 million for the three months ended September 30, 2018. This change is related to an increase in reimbursable expenses related to our contract with BARDA.

Research and Development Expenses

For the three months ended September 30, 2019, our research and development expenses decreased to $7.5 million compared to $11.9 million for the three months ended September 30, 2018. The decrease of $4.4 million, or 37.3%, is primarily related to the following:

- a decrease of $4.9 million mainly related to the discontinuation of both the oral and IV BCV development programs and CMX521 for norovirus;
- a decrease of $1.5 million in compensation expenses as headcount was reduced as part of the Company's restructuring activities in May 2019; offset by
- an increase of $2.1 million in expenses primarily related to the conduct of animal studies in the smallpox program.

General and Administrative Expenses

For the three months ended September 30, 2019, our general and administrative expenses decreased to $4.0 million compared to $5.2 million for the three months ended September 30, 2018. The decrease of $1.2 million, or 22.4%, is primarily related to the following:

- a decrease of $1.6 million in compensation expenses due to the Company's restructuring activities in May 2019; and
- a decrease of $0.4 million in expenses related to commercial readiness; offset by
- an increase of $1.0 million related to business development expenses and to out-license BCV for non-smallpox indications.

Acquired In-Process Research and Development

We recorded $65.0 million of acquired in-process research and development expenses for the three months ended September 30, 2019, which included $30.0 million for an upfront payment to Cantex, $34.9 million related to the fair value of common stock issued to Cantex, and $0.1 million related to Cantex transaction costs consisting primarily of legal and professional fees.

Interest Income and Other, Net

For the three months ended September 30, 2019, our interest income increased to $0.8 million compared to $0.6 million for the three months ended September 30, 2018. This increase is attributable to increased interest earned on our cash and investments.

Comparison of the Nine Months Ended September 30, 2019 and September 30, 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and September 30, 2018, together with the changes in those items (in thousands except percentages):

	Nine Months Ended September 30,		Dollar Change	% Change
	2019	2018	Increase/(Decrease)	
Contract revenue	$ 5,752	$ 2,352	$ 3,400	144.6 %
Operating expenses:				
Research and development	34,795	39,963	(5,168)	(12.9)%
General and administrative	18,022	18,575	(553)	(3.0)%
Acquired in-process research and development	65,045	—	65,045	*
Total operating expenses	117,862	58,538	59,324	101.3 %
Loss from operations	(112,110)	(56,186)	(55,924)	99.5 %
Other (expense) income:				
Interest income and other, net	3,037	1,668	1,369	82.1 %
Net loss	$ (109,073)	$ (54,518)	$ (54,555)	100.1 %

* Not meaningful or not calculable

Contract Revenue

For the nine months ended September 30, 2019, total contract revenue increased to $5.8 million compared to $2.4 million for the nine months ended September 30, 2018. The increase of $3.4 million, or 144.6%, is related to an increase in reimbursable expenses under our contract with BARDA.

Research and Development Expenses

For the nine months ended September 30, 2019, our research and development expenses decreased to $34.8 million compared to $40.0 million for the nine months ended September 30, 2018. The decrease of $5.2 million, or 12.9%, is primarily related to the following:

- a decrease of $6.5 million in expenses related to the discontinuation of both the oral and IV BCV development programs and CMX521 for norovirus;
- a decrease of $1.3 million in legal fees and operational expenses; and
- a decrease of $0.6 million in compensation expenses; offset by
- an increase of $3.1 million in expenses primarily related to the conduct of animal studies in the small pox program.

General and Administrative Expenses

For the nine months ended September 30, 2019, our general and administrative expenses decreased to $18.0 million compared to $18.6 million for the nine months ended September 30, 2018. The decrease of $0.6 million, or 3.0%, is primarily related to the following:

- a decrease of $2.7 million in expenses related to commercial readiness; offset by
- an increase of $1.8 million related to business development expenses and to out-license BCV for non-smallpox indications.

Acquired In-Process Research and Development

We recorded $65.0 million of acquired in-process research and development expenses for the three months ended September 30, 2019, which included $30.0 million for an upfront payment to Cantex, $34.9 million related to the fair value of common stock issued to Cantex, and $0.1 million related to Cantex transaction costs consisting primarily of legal and professional fees.

Interest Income and Other, Net

For the nine months ended September 30, 2019, our interest income and other, net increased to $3.0 million compared to $1.7 million for the nine months ended September 30, 2018. This increase is attributable to increased interest earned on our cash and investments.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2019, we had capital available to fund operations of approximately $116.7 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. We have incurred losses since our inception in 2000 and as of September 30, 2019, we had an accumulated deficit of $665.3 million. We anticipate that we will continue to incur losses for at least the next several years.

On November 8, 2017, we entered into an at-the-market (ATM) sales agreement with Cowen and Company, LLC to sell up to $75 million of our common stock under a shelf registration statement filed in November 2017. As of December 31, 2018, we had sold an aggregate of 2.8 million shares of common stock pursuant to the ATM at a weighted average price per share of $4.00 for net offering proceeds of $10.9 million. We have not sold any shares of our common stock pursuant to the ATM to-date in 2019.

We cannot assure that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs, and any launch and other commercialization expenses for any of our products that may receive marketing approval. We cannot assure you that we will successfully develop or commercialize our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

We believe that our existing cash, cash equivalents, and investments will enable us to fund our current operating expenses and capital requirements for at least the next 12 months. However, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate.

Cash Flows

The following table sets forth the significant sources and uses of cash (in thousands):

	Nine Months Ended September 30,	
	2019	**2018**
Cash sources and uses:		
Net cash used in operating activities	$ (71,712)	$ (45,425)
Net cash provided by investing activities	9,611	39,050
Net cash provided by financing activities	344	10,818
Net (decrease) increase in cash and cash equivalents	$ (61,757)	$ 4,443

Operating Activities

Net cash used in operating activities of $71.7 million for the nine months ended September 30, 2019 was primarily the result of our $109.1 million net loss and the change in operating assets and liabilities, partially offset by the add-back of non-cash expenses. The change in operating assets and liabilities includes a decrease of $3.1 million in accounts payable and accrued liabilities, an increase in accounts receivable of $1.5 million related to work on the BARDA contract, partially offset by a decrease in prepaid expenses and other assets of $0.2 million. Non-cash expenses included add-backs of $34.9 million for the fair value of common stock issued in relation to the Cantex license agreement, $8.0 million for share-based compensation and $0.5 million of depreciation of property and equipment, offset by $1.6 million of amortization of discount/premium on investments. Net cash used in operating activities of $45.4 million for the nine months ended September 30, 2018 was primarily the result of our $54.5 million net loss and the change in operating assets and liabilities, partially offset by the add-back of non-cash expenses of $10.6 million for share-based compensation and $0.7 million of depreciation of property and equipment. The change in operating assets and liabilities includes a decrease of $3.6 million in accounts payable and accrued liabilities, partially offset by a decrease in accounts receivable of $1.4 million related to work on the BARDA contract.

Investing Activities

Net cash provided by investing activities of $9.6 million for the nine months ended September 30, 2019 was primarily the result of the maturity of $127.0 million in short-term investments and the sale of $13.1 million in short-term investments, partially offset by the purchase of $130.4 million in short-term investments. Net cash provided by investing activities of $39.1 million for the nine months ended September 30, 2018 was primarily the result of the sales and maturities of $104.5 million in short-term investments partially offset by the purchase of $59.3 million in short-term investments and $6.0 million in long-term investments.

Financing Activities

Net cash provided by financing activities of $0.3 million for the nine months ended September 30, 2019 was primarily the result of $0.4 million in proceeds from the exercise of stock options and stock purchases through our ESPP. Net cash provided by financing activities of $10.8 million for the nine months ended September 30, 2018 was the result of $10.5 million in proceeds from issuance of common stock, $0.7 million in proceeds from the exercise of stock options and stock purchases through our ESPP offset by $0.4 million of payments of deferred offering costs.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” as contained in our Annual Report on Form 10-K for the year ended December 31, 2018 filed by us with the SEC on March 5, 2019.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We do not believe that our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposit do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain certain amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations for the three and nine months ended September 30, 2019 or September 30, 2018.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of September 30, 2019, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

We routinely review our internal control over financial reporting and from time to time make changes intended to enhance the effectiveness of our internal control over financial reporting. We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal control over financial reporting on an ongoing basis and will take action as appropriate. There have been no changes to our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the third quarter of 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained elsewhere in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 5, 2019.

Risks Related To Our Financial Condition and Need For Additional Capital

We are evaluating external assets to build our pipeline of product candidates and there can be no assurance that we will be successful in identifying or completing a transaction for a candidate, that any such transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.*

Earlier this year, we initiated a review of external assets that could be added to our pipeline of product candidates. In July 2019, in connection with this process, we entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which we acquired exclusive worldwide rights to develop and commercialize, for any and all uses, a glycosaminoglycan biologic known as dociparstat (DSTAT), which is currently being studied for the treatment of acute myeloid leukemia (AML) and, potentially, other serious diseases. Under the terms of the license agreement, we will be responsible for, and bear the future costs of, worldwide development and commercialization of DSTAT. These costs will be substantial, and we may require additional capital in order to pursue the development and commercialization of DSTAT as planned. Moreover, the anticipated benefits of our license to DSTAT may never be realized due to the various risks and uncertainties associated with drug development detailed elsewhere in the following risk factors.

In addition to DSTAT, we may in-license or acquire additional assets, engage in a merger or acquisition transaction, issue additional shares of our common stock, or engage in other potential actions designed to maximize stockholder value. Our continuing review of external assets may not result in the identification or consummation of any transaction. The process of reviewing external opportunities may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying, evaluating, negotiating, and consummating potential transactions. There can be no assurance that any potential additional transaction, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. In addition, once any potential additional transaction is consummated, we are likely to incur substantial costs associated with future development and testing of any new product candidate, which may require us to raise additional capital.

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

We are a biopharmaceutical company focused primarily on developing DSTAT for the treatment of AML and brincidofovir (BCV) for the treatment of smallpox. We have incurred significant net losses in each year since our inception, including net losses of $109.1 million and $54.5 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of approximately $665.3 million.

To date, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, through government funding, licensing fees and debt. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We have not completed development of any product candidates. We expect to continue to incur losses and negative cash flows for the foreseeable future. The size of our losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. In particular, we expect to incur substantial expenses as we seek to:

- initiate development and manufacturing activities of DSTAT for the treatment of AML and other potential indications;
- terminate our development activities of BCV for indications other than smallpox, including closing the AdAPT and IV studies of BCV;
- continue the development of BCV for the treatment of smallpox as a medical countermeasure;
- obtain regulatory approvals for DSTAT and BCV;
- scale-up manufacturing capabilities to commercialize DSTAT and BCV in the event we receive regulatory approval;
- identify and in-license additional product candidates to expand our research and development pipeline;
- maintain, expand and protect our intellectual property portfolio; and
- continue our internal research and development efforts and seek to discover additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including acquiring or discovering product candidates, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities.

To date, we have not obtained regulatory approval for any product candidate, and none of our product candidates have been commercialized. We may never succeed in developing or commercializing any product candidate. If we do not successfully develop or commercialize any product candidate, or if revenues from any products that do receive regulatory approvals are insufficient, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market a product candidate in the United States, our revenues are also dependent upon the size of markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success outside of the United States.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates.*

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development, obtain the necessary regulatory approvals and commercialize product candidates. We do not anticipate generating revenues from product sales for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our success in:

- obtaining favorable results for and advancing the development of DSTAT for the treatment of AML and BCV for the treatment of smallpox;
- obtaining United States and foreign regulatory approval(s) for DSTAT and BCV;
- generating, licensing or otherwise acquiring a pipeline of product candidates which progress to clinical development, regulatory approval, and commercialization.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and achieve product sales. Our anticipated development costs would likely increase if we do not obtain favorable results or if development of any product candidate is delayed. In particular, we would likely incur higher costs than we currently anticipate if development of any product candidate is delayed because we are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate, or we decide to conduct additional studies or trials for strategic reasons.

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

In addition, any product candidate, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. Even if any product candidate is approved for commercial sale, we anticipate incurring significant costs in connection with commercialization. As a result, we cannot assure you that we will be able to generate revenues from sales of any approved product candidate, or that we will achieve or maintain profitability even if we do generate sales.

If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs, seek corporate partners for the development of our product development programs or relinquish or license on unfavorable terms, our rights to technologies or product candidates.*

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We believe that our existing capital available to fund operations will enable us to fund our current operating expenses and capital requirements for at least the next twelve months. Changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate, and our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expected, or because the FDA or foreign regulatory authorities require us to perform studies or trials in addition to those that we currently anticipate.

In July 2019, we entered into a License and Development Agreement with Cantex in which we acquired an exclusive worldwide license to develop and commercialize DSTAT. We plan to initiate a Phase 3 clinical trial of DSTAT for the treatment of AML in mid-2020 subject to discussions with FDA.

We are also pursuing additional external opportunities to build our pipeline of product candidates, and we may need to raise additional funds if we identify additional product candidates other than DSTAT and BCV, which we may obtain through one or more equity offerings, debt financings, government or other third-party funding, strategic alliances and licensing or collaboration arrangements.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize DSTAT, BCV, or any other product candidate. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of DSTAT, BCV or any other product candidate;
- seek corporate partners for DSTAT, BCV, or any other product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects and on our ability to develop our product candidates.

Risks Related To Clinical Development and Regulatory Approval

Our product candidates, DSTAT and* BCV*, are still under clinical development for the treatment of smallpox, AML and other potential indications, respectively, and may not obtain regulatory approval or be successfully commercialized.*

We have not marketed, distributed or sold any products. Our product candidates are DSTAT, which we are developing for the treatment of AML and other potential indications and BCV, which we continue to develop for the treatment of smallpox as a medical countermeasure. We plan to initiate a Phase 3 clinical trial of DSTAT for the treatment of AML in mid-2020 subject to discussions with FDA.

There is no guarantee that our current or future clinical trials will be approved by regulators, and no guarantee that they will be completed or, if completed, will be successful, or if successful, will result in an approval for the sale of any of our product candidates. The success of each of DSTAT and BCV will depend on several factors, including the following:

- acceptance of data from our studies of oral BCV in animal models, including data necessary to bridge to a recommended human dose, by the FDA and foreign regulatory bodies;

- reaching agreement with the FDA on the design and conduct of a pivotal Phase 3 clinical trial to support approval of DSTAT;
- receipt of marketing approvals from the FDA and corresponding regulatory authorities outside the United States;
- establishing manufacturing capabilities necessary for a registration trial and commercialization of DSTAT;
- establishing commercial manufacturing capabilities for BCV;
- acceptance of the product, if approved for marketing;
- effectively competing with other therapies;
- a continued acceptable safety profile of the product following approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize BCV, which would materially harm our business.

We have never obtained regulatory approval for a drug and we may be unable to obtain, or may be delayed in obtaining, regulatory approval for DSTAT and* BCV.

We have never obtained regulatory approval for a drug. It is possible that the FDA and/or foreign health authorities, such as the EMA, may refuse to accept our NDA (or corresponding foreign application) for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval of DSTAT, BCV or both.

Through our continuing development contract with BARDA, we recently completed the in-life segment of our second rabbitpox efficacy study as well as a pivotal efficacy study in the mouse model (ectromelia virus). We believe that efficacy data from these models could support the approval of BCV for the treatment of smallpox. The data from these trials is subject to on-going confirmatory studies and audit. In addition, we are preparing data necessary to bridge to a recommended human dose.

In July, we entered into a license agreement with Cantex where we acquired an exclusive license to global development and commercialization rights to DSTAT. We plan to initiate a Phase 3 clinical trial of DSTAT for the treatment of AML in mid-2020 subject to discussions with FDA.

We have not yet reached agreement with the FDA or foreign regulators regarding the adequacy of these planned studies, for either DSTAT or BCV, with respect to a potential approval for marketing. We may be required to conduct additional clinical, nonclinical or manufacturing validation studies and submit those data before reconsideration of our application occurs. Depending on the extent of these or any other required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA and/or foreign health authorities to approve our NDA or foreign application.

Any delay in obtaining, or an inability to obtain, regulatory approvals could prevent us from generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for DSTAT and BCV, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We depend on the successful completion of clinical trials for our product candidates, including DSTAT and* BCV. *The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.*

Before obtaining regulatory approval for the sale of our product candidates, including BCV, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- animal efficacy studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional animal efficacy studies or abandon development programs;
- we might be required to change one of our clinical research organizations (CROs) during ongoing clinical programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- we may encounter agency or judicial enforcement actions which impact our clinical trials;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates, including DSTAT and BCV. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for either or both of DSTAT and BCV may be adversely impacted.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.*

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in a delay or unsuccessful completion of clinical trials, including our currently planned or future clinical trials for either DSTAT, BCV or both, include:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining, or failure to obtain, regulatory approval of Investigational New Drug applications or to commence a trial;
- delays in reaching agreement with the FDA and foreign health authorities on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays caused by disagreements with existing CROs and/or clinical trial sites;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining, or failure to obtain, required IRB or ethics committee (EC) approvals covering each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- clinical sites declining to participate or dropping out of a trial to the detriment of enrollment;
- agency or judicial enforcement actions against us;
- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

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

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

Adverse events (AEs) caused by our product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. For example, subjects enrolled in our clinical trials for BCV have experienced gastrointestinal AEs and liver-related safety laboratory value changes. In addition, BCV is related to the approved drug cidofovir, a compound which has been shown to result in significant renal toxicity and impairment following use. As a second example, subjects enrolled in clinical trials for DSTAT have experienced febrile neutropenia and liver enzyme elevations. If an unacceptable frequency and/or severity of AEs are reported in our clinical trials for our product candidates, our ability to obtain regulatory approval for product candidates may be negatively impacted.

If any of our approved products cause serious or unexpected side effects prior to or after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may approve the product only with a risk evaluation and mitigation strategy (REMS), potentially with restrictions on distribution and other elements to assure safe use (ETASU);
- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize any of our product candidates and we cannot, therefore, predict the timing of any future revenue from DSTAT or* BCV.

We cannot commercialize our product candidates, including DSTAT and BCV, until the appropriate regulatory authorities have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for either of our product candidates. Additional delays in the United States may result if either DSTAT or BCV is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In the EU context, an Oral Explanation during MAA review could extend approval timelines and result in a Negative Opinion. A re-examination procedure is available in the EU whereby a Negative Opinion could be over-turned and become a Positive Opinion. New rapporteurs would be selected for the product. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates.

Even if we obtain regulatory approval for DSTAT and* BCV*, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.*

Even if we obtain regulatory approval, the granting authority may still impose significant restrictions on the indicated uses, distribution or marketing of our product candidates, including DSTAT and BCV, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for our product candidates, including DSTAT and BCV, will likely include restrictions on use due to the specific patient population and manner of use in which the drug was evaluated and the safety and efficacy data obtained in those evaluations. In addition, the distribution of DSTAT and BCV may be tightly controlled through a REMS with ETASU, which are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient. Some actions may also be required in order for the patient to continue on treatment. For example, the label for BCV may be required to include a boxed warning, or “black box,” regarding BCV being carcinogenic, teratogenic and impairing fertility in animal studies, as well as a contraindication in patients who have had a demonstrated clinically significant hypersensitivity reaction to BCV or cidofovir or any component of the formulation. The BCV labeling may also include warnings or black boxes pertaining to gastrointestinal AEs or liver-related safety laboratory value changes.

DSTAT, BCV and any other product candidates will also be subject to additional ongoing regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. In the United States, the holder of an approved NDA is obligated to monitor and report AEs and

any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. If a REMS is required, the NDA holder may be required to monitor and evaluate those in the healthcare system who are responsible for implementing ETASU measures. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Moreover, EU and member countries impose strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the U.S., EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by regulatory authorities for compliance with cGMP, and adherence to commitments made in the application. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any product candidates, a regulatory agency may:

- issue an untitled or warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending application or supplements to an application submitted by us;
- recall and/or seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize DSTAT, BCV and any other product candidates and inhibit our ability to generate revenues.

Obtaining FDA approval for any one of our products in the United States does not mean we will ever obtain approval for or commercialize DSTAT,* BCV, *or any other products outside of the United States, nor does approval of any of our products outside the United States mean we will ever obtain approval for or commercialize any other products inside the United States, all of which could limit our ability to realize their full market potential.*

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in any markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

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

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

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

- the federal healthcare anti-kickback statute which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws and the Federal Civil Monetary Penalties Act, including the Federal Civil False Claims Act (False Claims Act) which permit private individuals to bring a civil action on behalf of the federal government to enforce certain of these laws thought civil whistleblower or *qui tam* actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates;
- the General Data Protection Regulation (GDPR), which impose obligations on companies in relation to the handling of personal data of individuals within the EU, along with related national legislation;
- mandated physician payments reporting laws and/or requirements throughout global jurisdictions, including EU member states, in which we conduct research and development and/or other business activities;
- the FDCA which prohibits, among other things, the adulteration or misbranding of drugs and devices;
- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies to report to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payers, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

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

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

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

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payers.

More recently, in March 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. However, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. In July 2018, CMS published a final rule permitting further collection and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace ACA will impact ACA and our business. Congress also could consider additional legislation to repeal or repeal and replace other elements of the ACA.

Although it is too early to determine the full effect of the ACA, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs. This "Blueprint" contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services (DHHS) has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing other measures under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the DHHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price that we receive for any future approved product. We cannot predict what healthcare reform initiatives may be adopted in the future.

Risks Related to Our Reliance on Third Parties

We rely on third-party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidates.*

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing with respect to either DSTAT or BCV. In the past, we have relied on third-party manufacturers for supply of our preclinical and clinical drug supplies. We expect that in the future we will continue to rely on such manufacturers for drug supply that will be used in clinical trials of both DSTAT and BCV, and for commercialization of any of our product candidates that receive regulatory approval.

In July 2019, we were assigned Cantex's rights under a supply agreement with Scientific Protein Laboratories LLC (SPL) pursuant to which SPL will exclusively produce DSTAT for us through October 2030. We have agreed that SPL will be our exclusive provider of DSTAT bulk drug substance during the term of the agreement.

Our reliance on third-party manufacturers entails risks, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA or equivalent foreign regulator action, including injunction, recall, seizure, or total or partial suspension of production.

We rely on limited sources of supply for the drug components for each of DSTAT and* BCV*, and any disruption in the chain of supply for either of these product candidates may cause delays in their development and commercialization.*

Manufacturing of drug components is subject to certain FDA and comparable foreign qualifications with respect to manufacturing standards. We have validated the BCV drug substance manufacturing process at our selected contractor that will produce the commercial supply and possible procurement supply of drug substance. We have selected our BCV commercial and possible procurement tablet and suspension manufacturers to optimize tablet and suspension formulation production to meet forecasted commercial and procurement demand. There can be no assurance that such transfer to the selected vendors will be successful. We plan to validate the DSTAT drug substance and drug product processes prior to regulatory approval. It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified as vendors for both DSTAT and BCV with the FDA. If supply from an approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new drug substance or drug product supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of DSTAT and BCV, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials for DSTAT and BCV may be delayed, which could inhibit our ability to generate revenues.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization of DSTAT and* BCV.

We have a validated process for drug substance and drug product production for BCV.

We plan to validate DSTAT drug substance and drug product processes prior to approval at our selected vendors. It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified as vendors for DSTAT with the FDA.

The validation processes, along with ongoing stability studies and analyses we are conducting, may reveal difficulties in our processes which could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of DSTAT and BCV. In the future, we may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical program and regulatory approval for DSTAT and BCV, increases in our operating expenses, or failure to obtain or maintain approval for either DSTAT, BCV or both.

We depend on SymBio for developing and commercializing BCV for human diseases other than smallpox.*

In 2019, we entered into a licensing arrangement with SymBio, whereby SymBio is responsible for the future development and commercialization of BCV. Under this arrangement, SymBio is responsible for conducting preclinical studies and clinical trials, obtaining required regulatory approvals for BCV in non-smallpox indications, and manufacturing and commercializing BCV in those indications. Our right to receive milestone payments under the licensing agreement depends on the achievement of certain development, regulatory and commercial milestones by SymBio and our ability to receive royalties under the agreement depends on SymBio's successful commercialization of BCV in the licensed indications.

The development and commercialization of the non-smallpox uses of BCV in humans and our ability to receive potential milestones and royalty payments under the license agreement with SymBio, would be adversely affected if SymBio:

- lacks or does not devote sufficient time and resource to the development and commercialization of BCV;
- lacks or does not devote sufficient capital to fund the development and commercialization of BCV;
- develops, either alone or with others, products that compete with BCV;
- fails to gain the requisite regulatory approvals for BCV;
- does not successfully commercialize BCV;
- does not conduct its activities in a timely manner;
- terminates its license with us;
- does not effectively pursue and enforce intellectual property rights relating to BCV; or
- merges with a third-party that wants to terminate the collaboration.

We have limited or no control over the occurrence of any of the foregoing. Furthermore, disagreements with SymBio could lead to litigation or arbitration, which could be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization milestones and royalties based on further development and sales of BCV.

We rely on third parties to conduct, supervise and monitor our clinical studies and related data, and if those third parties perform in an unsatisfactory manner, it may harm our business.*

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical programs for DSTAT, BCV and any other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's guidance for clinical trials conducted within the jurisdiction of the United States (or the foreign regulatory authority equivalent for clinical trials conducted outside the jurisdiction of the United States), which follows the International Council for Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize DSTAT, BCV or any other product candidates. Disagreements with our CROs over contractual issues, including performance, compliance or compensation could lead to termination of CRO agreements and/or delays in our clinical program and risks to the accuracy and usability of clinical data. As a result, our financial results and

the commercial prospects for DSTAT, BCV and any other product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of DSTAT,* BCV *and any other product candidates will depend upon the acceptance of these products by the medical community, including physicians, patients, pharmacists and health care payers.*

If any of our product candidates, including DSTAT and BCV, receive marketing approval, they may nonetheless not gain sufficient market acceptance by physicians, patients, healthcare payers and others in the medical community. If these products do not achieve an adequate level of market acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, including DSTAT and BCV, will depend on a number of factors, including:

- demonstration of clinical safety and efficacy in our clinical trials;
- relative convenience, ease of administration and acceptance by physicians, patients, pharmacists and health care payers;
- prevalence and severity of any AEs;
- limitations or warnings contained in the FDA-approved labeling from Regulatory Authorities such as the FDA and EMA for the relevant product candidate;
- availability, efficacy and safety of alternative treatments;
- price and cost-effectiveness;
- effectiveness of our or any future collaborators' or competitor's sales and marketing strategies;
- ability to obtain hospital formulary approval;
- ability to ensure availability for product through appropriate channels;
- ability to maintain adequate inventory; and
- ability to obtain and maintain sufficient third-party coverage and adequate reimbursement, which may vary from country to country.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.*

We currently do not have an organization for the sales and distribution of pharmaceutical products. The cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, including DSTAT and BCV, we must establish our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our product candidates, including BCV.

Our strategy for DSTAT and BCV is to establish a specialty sales force and/or collaborate with third parties to promote the product to healthcare professionals and third-party payers in the United States and elsewhere. We may elect to launch with a contract sales organization and utilize accompanying commercial support services provided by a contract sales organization. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the distribution and sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that are not covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales, including sales of DSTAT and BCV, will be adversely affected.

Establishing an internal or contract sales force involves many challenges, including:

- recruiting and retaining talented people;
- training employees that we recruit;
- establishing compliance standards;
- setting the appropriate system of incentives;
- managing additional headcount;
- ensuring that appropriate support functions are in place to support sales force organizational needs; and
- integrating a new business unit into an existing corporate architecture.

If we are unable to establish our own sales force or negotiate a strategic partnership for the commercialization of DSAT and BCV in any markets, we may be forced to delay the potential commercialization of DSTAT and BCV in those markets, reduce the scope of our sales or marketing activities for DSAT and BCV in those markets or undertake the commercialization activities for DSTAT and BCV in those markets at our own expense. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring DSTAT and BCV to market or generate product revenue. Limited or lack of funding will impede our ability to achieve successful commercialization.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing and market access personnel.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.*

If our product candidates are approved for commercialization, we may enter into agreements with third parties to market those product candidates outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in the EU and other foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory and labor requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- differing payer reimbursement regimes, governmental payers or patient self-pay systems and price controls;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions, or similar anti-bribery or anti-corruption laws and regulations.

We have limited experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the individual countries in Europe with which we will need to comply. Many U.S.-based biopharmaceutical companies have found the process of marketing their own products outside the United States to be very challenging.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.*

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our competitors have substantially greater financial, technical, commercial and other resources, such as larger research and development staff, stronger intellectual property portfolios and experienced marketing and manufacturing organizations and

established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug products that are more effective or less costly than DSTAT and BCV or any other drug candidate that we are currently developing or that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the same indications. Therefore, our ability to compete successfully will depend largely on our ability to:

- discover and develop medicines that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates, including DSTAT and BCV, are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain and successfully defend and enforce patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines;
- deliver a competitive value proposition compared to established competition and/or competitors who will enter the market before or after any of our product candidates, including DSTAT and BCV; and
- negotiate competitive pricing and reimbursement with third-party payers.

The availability of our competitors' products could affect the price we are able to charge, for DSTAT, BCV, and any other product candidate we develop. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates, including DSTAT and BCV, less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

New technologies or procedures could be developed that would change or restrict the number of patients undergoing hematopoietic cell or solid organ transplants. A reduction in the number of transplants could negatively impact our commercial business by decreasing sales of our products and limiting peak sales potential.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates. Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our research methodology or that of our collaboration partners may be unsuccessful in identifying potential product candidates;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- our collaboration partners may change their development profiles for potential product candidates or abandon a therapeutic area.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new

product candidates require substantial technical, financial and human resources. We may focus our research efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.*

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other countries. If this were to occur, early generic competition could be expected against DSTAT, BCV, and any other product candidates we may develop. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability, scope or ownership, which may result in such patents, or our rights to such patents, being narrowed or invalidated.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold or license with respect to DSTAT and BCV fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable, will go unthreatened by third parties or will adequately protect our products and product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market DSTAT and BCV under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to DSTAT, BCV or any other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be possible. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Further, the laws of some foreign countries do not protect patents and other proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property abroad. We may also fail to pursue or obtain patents and other intellectual property protection relating to our products and product candidates in all foreign countries.

Finally, certain of our activities and our licensors' activities have been funded, and may in the future be funded, by the U.S. federal government. When new technologies are developed with U.S. federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry.

In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts or otherwise affect our business.*

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of DSTAT, BCV and/or any other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter-claims against us.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in a litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process.

While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, we may lose our rights and our competitors might be able to enter the market, which would have a material adverse effect on our business.

Risks Related to Our United States Government Contracts and Grants

There can be no assurances that we will be able to enter into a contract with BARDA to act as the sole supplier for the procurement of* BCV *for the treatment of smallpox.*

In April 2015, BARDA posted a notice of intent to use other than full and open competition to award a sole source contract to us for the procurement of BCV for the treatment of smallpox. In May 2015, BARDA posted an approved justification for the use of other than full and open competition for the contract. In July 2015, BARDA issued a RFP entitled “2015 Procurement of a Second Smallpox Antiviral Drug for the Strategic National Stockpile.” In August 2015, we submitted a response to the RFP and we subsequently engaged in discussions with BARDA regarding our response. The issuance of that RFP did not culminate with agreement for the sole source supply of BCV for the Strategic National Stockpile (SNS).

We remain in discussions with BARDA regarding the potential to supply BCV to the SNS, however, there can be no assurances that a future RFP for BCV procurement will be issued.

Furthermore, in the event that BARDA issues an RFP for procurement of a smallpox antiviral therapeutic, there can be no assurance that we would reach agreement with BARDA on terms related to the manufacture and delivery of BCV to the SNS. Among the material terms to be negotiated and agreed to are: price, volume, and payment and delivery schedules, as we currently do not have BCV commercial product in inventory that would be available for immediate delivery.

Unfavorable provisions in government contracts, including our contract with BARDA, may harm our business, financial condition and operating results.

United States government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our contract with BARDA, the U.S. government has the power to unilaterally:

- audit and object to any BARDA contract-related costs and fees on grounds that they are not allowable under the FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or extending our existing contract based on violations or suspected violations of laws or regulations;

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

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

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

- FAR, and agency-specific regulations supplements to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts and implement federal procurement policy in numerous areas, such as employment practices, protection of the environment, accuracy and retention periods of records, recording and charging of costs, treatment of laboratory animals and human subject research;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

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

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

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

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

- termination of contracts;

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

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

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

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

Risks Related to Our Business Operations and Industry

We may not realize the expected benefits of our cost-saving initiatives.*

Reducing costs is a key element of our current business strategy. As a consequence of terminating development activities related to the oral and IV programs for BCV, we initiated a reduction to our workforce. Personnel reductions were initiated across our entire organization that have resulted in a remaining workforce of approximately 40 full-time employees. The principal objective of the reduction in workforce was to enable us to focus our financial resources on the continued development of BCV for smallpox and the evaluation of external opportunities to build our pipeline of product candidates, including our recently completed transaction with Cantex described above.

In connection with the reduction in workforce, we expect to record an aggregate charge related to one-time termination benefits of approximately $3.3 million in 2019. If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely impact our results of operations and financial condition.

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

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

A possible consequence of both activism and legislation in this area is the need for us to initiate an unanticipated expanded access program or to make DSTAT or BCV more widely available sooner than anticipated. We are a small company with limited resources and unanticipated trials or access programs could result in diversion of resources from our primary goals.

In addition, patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and have exhausted all other available therapies. The risk for serious adverse events in this patient population is high which could have a negative impact on the safety profile of DSTAT and BCV, which could cause significant delays or an

inability to successfully commercialize DSTAT and BCV, which could materially harm our business. We may also need to restructure or pause ongoing compassionate use and/or expanded access programs in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of DSTAT and BCV, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs. The BCV compassionate use program is expected to end in mid-2020 when this current clinical supply is no longer available.

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

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

We recently hired a new Chief Executive Officer and a new Chief Business Officer and our ability to successfully manage this transition and our recently announced corporate restructuring could impact our business.*

Effective April 8, 2019, we hired Michael Sherman as our President and Chief Executive Officer, and hired Michael Andriole as our Chief Business Officer. Leadership transitions can be difficult to manage and may cause disruptions to our operations. The leadership transition, coupled with our recently announced corporate restructuring, may also increase the likelihood of turnover among our employees and result in changes in our business strategy, which may create uncertainty and negatively impact our ability to execute our business strategy quickly and effectively. The leadership transition and restructuring may also impact our relationships with customers and suppliers, and create uncertainty among investors, employees, creditors and others concerning our future direction and performance. Any significant disruption, uncertainty or change in business strategy could adversely affect our business, financial condition and operating results.

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

We are highly dependent on the principal members of our executive team. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. To help attract, retain, and motivate qualified employees, we use share-based incentive awards such as employee stock options and restricted stock units. Due to the decline in our stock price that has occurred since December 2015, a large percentage of the options held by our employees are underwater. As of September 30, 2019, approximately 78% of all outstanding options had an exercise price above the closing price of the stock on that date. As a result, the current situation provides a considerable challenge to maintaining employee motivation, as well as creating a serious threat to retention until a recovery commences. If our share-based compensation ceases to be viewed as a valuable benefit, our ability to attract, retain, and motivate employees could be weakened, which could harm our results of operations.

We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of appropriately skilled executives in our industry, which is likely to continue. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, failure of any of our clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee may adversely affect the progress of our research, development and commercialization objectives.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us, which could also adversely affect the progress of our research, development and commercialization objectives.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.*

The use of our product candidates, including DSTAT and BCV, in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical studies;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates, including DSTAT and BCV; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently carry $15 million in product liability insurance covering our clinical trials. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Risks Related To Our Common Stock

The market price of our common stock is likely to be volatile, and you may not be able to resell your shares at or above your purchase price.*

The trading price of our common stock has been volatile, and is likely to continue to be volatile for the foreseeable future. Our stock price is subject to wide fluctuations in response to a variety of factors, including the following:

- results of clinical trials of our product candidates or those of our competitors;
- any delay in filing an application for any of our product candidates and any adverse development or perceived adverse development with respect to regulatory review of that application;
- failure to successfully develop and commercialize our product candidates, including DSTAT and BCV;
- termination of any of our license or collaboration agreements;
- any agency or judicial enforcement actions against us;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to our product candidates;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- significant lawsuits (including patent or stockholder litigation), and disputes or other developments relating to proprietary rights (including patents, litigation matters and our ability to obtain patent protection for our technologies);
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

Based upon shares of common stock outstanding as of September 30, 2019, our then executive officers, directors, 5% stockholders (known to us through available information) and their affiliates beneficially owned approximately 34.4% of our voting stock. Therefore, these stockholders have the ability to substantially influence us through this ownership position. For example, these stockholders, if they choose to act together, may be able to influence the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting expense and expend significant management efforts. In this or future years, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the Securities and Exchange Commission, The Nasdaq Stock Market or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.*

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

In July 2019, we entered into a license agreement with Cantex where we acquired an exclusive license to global development and commercialization rights to DSTAT. As partial consideration for our rights under the license agreement, we issued to Cantex 10,000,000 shares of our common stock. We are continuing to review additional potential transactions to add to our pipeline of product candidates, and these transactions could involve the issuance of additional shares of common stock or other equity securities.

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

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

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

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

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

Comprehensive tax reform could adversely affect our business and financial condition.*

On December 22, 2017, President Trump signed into law the Tax Act which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated in taxable years beginning after December 31, 2017, to 80% of current year taxable income, elimination of most carrybacks of net operating losses arising in taxable years ending after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

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

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

Our U.S. net operating loss, or NOL, carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs generated in tax years beginning after December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change U.S. tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have determined that a Section 382 ownership change occurred in 2002 and 2007 resulting in limitations of at least $64,000 and $762,000, respectively, of losses incurred prior to the respective ownership change dates. In addition, we have determined that another Section 382 ownership change occurred in 2013 with our IPO, our most recent private placement and other transactions that have occurred since 2007, resulting in a limitation of at least $6.7 million of losses incurred prior to the ownership change date. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, our pre-2018 NOL carryforwards may expire prior to being used, and our NOL carryforwards generated in 2018 and thereafter will be subject to a percentage limitation. In addition, it is possible that we have in the past undergone, and in the future may undergo, additional ownership changes that could limit our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes.

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

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

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

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

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the

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

Risks Related to Information Technology

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

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

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

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

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

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable laws and regulations. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

The following exhibits are filed as part of this report:

Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(1)	Amended and Restated Bylaws of the Registrant.
4.1(2)	Form of Common Stock Certificate of the Registrant.
10.1*	License and Development Agreement, dated July 26, 2019, by and between the Registrant and Cantex Pharmaceuticals, Inc.
10.2*	Supply Agreement, dated October 2, 2015, by and between the Registrant (as successor to Cantex Pharmaceuticals, Inc.) and Scientific Protein Laboratories LLC.
10.3*	License Agreement, dated September 30, 2019, by and between the Registrant and SymBio Pharmaceuticals Limited.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Certain confidential information contained in this exhibit, marked by brackets, has been omitted pursuant to Item 601 of Regulation S-K.

(1) Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867), filed with the SEC on April 16, 2013.

(2) Incorporated by reference to Chimerix, Inc.'s Registration Statement on Form S-1 (No. 333-187145), as amended.

SIGNATURES

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

CHIMERIX, INC.

November 5, 2019	By:	/s/ Michael A. Sherman
		Michael A. Sherman
		President and Chief Executive Officer
November 5, 2019	By:	/s/ Michael T. Andriole
		Michael T. Andriole
		Chief Business and Financial Officer

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

LICENSE AND DEVELOPMENT AGREEMENT

by and between

CANTEX PHARMACEUTICALS, INC.

and

CHIMERIX, INC.

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

LICENSE AND DEVELOPMENT AGREEMENT

This **LICENSE AND DEVELOPMENT AGREEMENT** (this "Agreement") is entered into as of July 26, 2019 (the "Effective Date") by and between **CANTEX PHARMACEUTICALS, INC.**, a Delaware corporation having an address at 1792 Bell Tower Lane, Weston, FL 33326 ("Licensor") and **CHIMERIX, INC.,** a Delaware corporation having an address at 2505 Meridian Parkway, Suite 100, Durham, NC 27713 ("Licensee"). Licensor and Licensee are sometimes referred to individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Licensor has rights to that certain 2-O, 3-O desulfated heparin polysaccharide known as CX-01;

WHEREAS, Licensee possesses resources and expertise in the development, manufacture, marketing and commercialization of pharmaceutical products; and

WHEREAS, Licensee desires to obtain from Licensor, and Licensor desires to grant to Licensee certain exclusive licenses in the Territory to research, Develop, make, have made, register, use, sell, offer for sale, distribute, import and export and otherwise Commercialize Products (as defined below) as set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

"Acquiror" has the meaning set forth in Section 15.5.

"Affiliate" means, with respect to either Party, any person, firm, trust, corporation, partnership or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party; for purposes of this definition, the term "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") meaning direct or indirect ownership of fifty percent (50%) or more, including ownership by one or more trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation, partnership or other entity or combination thereof, or the power to direct the management of such person, firm, trust, corporation, partnership or other entity or combination thereof.

"Affordable Care Act" means the Patient Protection and Affordable Care Act, 42 U.S.C. Sections 18001, et. seq. (2010), as amended.

"Agreement" has the meaning set forth in the Preamble.

"Alliance Manager" has the meaning set forth in Section 3.2(a).

"AML" means acute myeloid leukemia (also known as acute myelogenous leukemia).

"Bankruptcy Code" means, as applicable, the U.S. Bankruptcy Code, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or the bankruptcy laws of any Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or any applicable bankruptcy laws of any other country or Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

"Breaching Party" has the meaning set forth in Section 13.3(a).

"Business Day" means any day other than a day on which the commercial banks in New York City are authorized or required to be closed.

"Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term commences on the Effective Date and ends on the first to occur of March 31, June 30, September 30 and December 31 after the Effective Date, and the last Calendar Quarter ends on the last day of the Term.

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

"Change of Control" means, with respect to either Party, (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (b) a merger (including a reverse triangular merger), consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party, or any Affiliate that controls such Party directly or indirectly, immediately before such merger, consolidation, share exchange or other similar transaction ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, or (c) the acquisition by a person or entity, or group of persons or entities acting in concert, of more than fifty percent (50%) of the outstanding voting equity securities of such Party; in all cases of clauses (a)–(c), where such transaction is to be entered into with any person or group of persons other than the other Party or its Affiliates.

"Claims" has the meaning set forth in Section 11.1.

"Clinical Studies" means a research study using human subjects to evaluate biomedical or health-related outcomes, including but not limited to a Phase 1 Study, a Phase 2 Study, a Phase 3 Study or variations of such studies (e.g., Phase 2/3).

"CMC Information" means Information related to the chemistry, manufacturing and controls of a product, as specified by the FDA, EMA and other applicable Regulatory Authorities.

"Combination Product" has the meaning set forth in the definition of Net Sales.

"Commercialization", with a correlative meaning for "Commercialize" and "Commercializing", means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the commercialization and pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale and distribution of Product, including strategic marketing, sales force detailing, advertising, and market and Product support, and all customer support, Product distribution, invoicing and sales activities.

"Commercially Reasonable Efforts" means, with respect to a Party's obligations or tasks under this Agreement with respect to the performance of any activities by a Party hereunder, the level of efforts and resources that a company within the pharmaceutical industry and similarly situated to such Party would reasonably devote to a product of similar market potential or profit potential resulting from its own research efforts, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions (including Generic Product market penetration), the profitability of a Product in light of pricing and reimbursement issues, including rebates under risk sharing schemes, reference pricing, cost of goods, and all other relevant scientific, technical and commercial factors.

"Competitive Product" means 2-O, 3-O desulfated heparin (ODSH) for any use in any Field.

"Confidential Information" of a Party means any and all Information that is disclosed by or on behalf of such Party or its Affiliates to the other Party or its Affiliates under this Agreement, whether in oral, written, graphic, or electronic form, that can reasonably be expected by a Party to be treated as confidential.

"Control" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement), right or covenant to such material, Information, or intellectual property right, and in each case, has the ability to grant to the other Party access, a license or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

"CREATE Act" has the meaning set forth in Section 10.3(g)(i).

"CX-01" means a heparinoid that is substantially desulfated at the 2-O and 3-O positions, where the heparinoid is desulfated at least 90% and has an average molecular weight of about 8 kDa to about 15 kDa.

"Default Notice" has the meaning set forth in Section 13.3(a).

"Develop" or "Development" means all activities relating to preparing and conducting non-Clinical Studies, Clinical Studies, and regulatory activities (e.g. preparation of regulatory applications) that are necessary or useful to obtain and maintain Drug Approval of a Product.

"Development Plan" means the comprehensive written development plan that specifies all Development activities for Products, and includes a detailed timeline for performing those activities necessary to obtain Regulatory Approval in the Field in each Major Market Country (such timeline, the "Regulatory Plan"). For each Development activity specified in the Development Plan, the Development Plan will specify the Party that is responsible for such activity, the timeline for initiating and completing such activity and the budget for such activity.

"Development/Regulatory Milestones" has the meaning set forth in Section 8.2(a).

"Dispute" has the meaning set forth in Section 14.1.

"Dollars" or "$" means U.S. dollars.

"Drug Approval" means an approval granted by the appropriate Regulatory Authority to market a Product in the Field in any particular jurisdiction in the Territory; *provided*, "Drug Approval" includes any and all marketing authorizations in the EU but excludes any and all Pricing and Reimbursement Approvals.

"Effective Date" has the meaning set forth in the Preamble.

"EMA" means the European Medicines Agency or any successor entity.

"EU" means the European Union member states, as constituted on the Effective Date and as it may be expanded from time to time following such date. As of the Effective Date, the European Union member states are Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Notwithstanding the foregoing, the EU will at all times be deemed to include the United Kingdom, whether or not the United Kingdom remains a member state of the EU.

"FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended.

"FDA" means the U.S. Food and Drug Administration or any successor entity.

"Field" means any and all uses, including all uses in human and non-human animals.

"First Commercial Sale" means, with respect to a particular product in a given country or regulatory jurisdiction, the first sale for monetary value for use or consumption by the end user of such product to a Third Party in a given country or regulatory jurisdiction after Drug Approval has been obtained in such jurisdiction. Sales prior to receipt of Regulatory Approval for such product, such as so-called "treatment IND sales", "named patient sales", and "compassionate use sales" shall not be construed as a "First Commercial Sale".

"First Site Initiation" has the meaning set forth in Section 4.3(a)(i).

"GAAP" means U.S. generally accepted accounting principles, consistently applied.

"GCP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as such standards, practices and procedures may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"Generic Product" means, with respect to a Product (the "Reference Product"), any pharmaceutical product in a particular regulatory jurisdiction that (a) (i) contains the same active pharmaceutical ingredients as the Reference Product; (ii) is bioequivalent to the Reference Product as determined by the applicable Regulatory Authority in such jurisdiction; and (iii) has one or more Regulatory Authority-approved Indications in such jurisdiction equivalent to any of the Regulatory Authority-approved Indications for the Reference Product in such jurisdiction (except that the references to "such jurisdiction" in this subsection (iii) means, with respect to Regulatory Authority-approved Indications in the Territory, any one or more countries in the Territory); and (b) is sold in such jurisdiction by a Third Party that is not a Sublicensee of Licensee or its Affiliates, and is not otherwise authorized by Licensee or any of its Affiliates, Sublicensees or distributors to sell such product.

"GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"GMP" means the standards relating to current Good Manufacturing Practices for fine chemicals, active pharmaceutical ingredients, intermediates, bulk products or finished pharmaceutical products set forth in (a) 21 U.S.C. 351(a)(2)(B), in FDA regulations at 21 C.F.R. Parts 210 and 211 and in The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, or (b) the ICH Guidelines relating to the manufacture of active pharmaceutical ingredient and finished pharmaceuticals, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"Governmental Authority" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

"ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"ICH Guidelines" means the guidelines of the ICH.

"IND" means an Investigational New Drug Application with the FDA, as defined in the FD&C Act.

"Indemnified Party" has the meaning set forth in Section 11.3.

"Indemnifying Party" has the meaning set forth in Section 11.3.

"Indication" means any disease, disorder or condition that can be prevented, diagnosed or treated, or is otherwise approved in labeling for a pharmaceutical product by an applicable Regulatory Authority, in any area within the Field, including AML and MDS.

"Information" means all data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-Clinical Studies), CMC Information, Regulatory Materials, stability data, manufacturing data and other study data and procedures.

"Inventions" means all ideas, inventions, modifications, improvements or new uses, whether or not patentable, discovered, made, conceived, or reduced to practice in the course of activities contemplated by this Agreement.

"JAMS Rules" has the meaning set forth in Section 14.1.

"JDC" has the meaning set forth in Section 3.1(a).

"Laws" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

"Licensee" has the meaning set forth in the Preamble.

"Licensee Indemnitees" has the meaning set forth in Section 11.1.

"Licensee Inventions" has the meaning set forth in Section 9.1(a).

"Licensee Know-How" means all Information that (a) is necessary or useful for the Development, manufacture or Commercialization of a Product in the Field and (b) is Controlled by Licensee or its Affiliates during the Term; *provided*, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensee after the Effective Date due to a Change of Control of Licensee, except to the extent such Third Party's Information is Controlled by Licensee (or its Acquiror) or any of its other Affiliates and is necessary for the Development, manufacture or Commercialization of a Product and is used in respect of CX-01 or any Product in the Territory.

"Licensee Patent" means any Patent (other than a Licensor Patent) that (a) claims, generically or specifically, CX-01 or any Product, or the manufacture or use in the Field of CX-01 or any Product, and (b) which is Controlled by Licensee or its Affiliates during the Term; provided, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensee after the Effective Date due to a Change of Control of Licensee, except to the extent such Third Party's Information is Controlled by Licensee (or its Acquiror) or any of its other Affiliates and is necessary for the Development, manufacture or Commercialization of any Product and is used in respect of CX-01 or any Product in the Territory.

"Licensee Prosecuted Patents" has the meaning set forth in Section 9.3(a).

"Licensee Technology" means the Licensee Know-How and Licensee Patents.

"Licensor" has the meaning set forth in the Preamble.

"Licensor Indemnitees" has the meaning set forth in Section 11.2.

"Licensor Inventions" has the meaning set forth in Section 9.1(a).

"Licensor Know-How" means all Information that (a) is necessary or useful for the Development, manufacture or Commercialization of a Product in the Field and (b) (i) is Controlled by Licensor or its Affiliates as of the Effective Date or (ii) is Controlled by Licensor or its Affiliates during the Term; *provided*, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensor after the Effective Date due to a Change of Control of Licensor, except to the extent such Third Party's Information is Controlled by Licensor (or its Acquiror) or any of its other Affiliates and is necessary for the Development, manufacture or Commercialization of CX-01 or any Product and is used in respect of a Product in the Territory.

"Licensor Patent" means any Patent (other than a Licensee Patent) that (a) claims, generically or specifically, CX-01 or any Product, or the manufacture or use in the Field of CX-01 or any Product and (b) (i) is Controlled by Licensor or its Affiliates as of the Effective Date, which such Patents are set forth in Schedule 1 hereto, (ii) is Controlled by Licensor or its Affiliates during the Term and claims priority to a Patent Controlled by Licensor or its Affiliates as of the Effective Date, or (iii) is Controlled by Licensor or its Affiliates during the Term; *provided*, that the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensor after the Effective Date due to a Change of Control of Licensor, except to the extent such Third Party's Information is Controlled by Licensor (or its Acquiror) or any of its other Affiliates and is necessary for the Development, manufacture or Commercialization of a Product and is used in respect of CX-01 or any Product in the Territory.

"Licensor Technology" means the Licensor Know-How and the Licensor Patents.

"Major Market Countries" means the following countries: the U.S., France, Germany, Italy, Spain, the United Kingdom and Japan.

"Market Exclusivity" means, on a country-by-country and Product-by-Product basis, the period of time during the Royalty Term commencing on the date as of which [*].

"Material Impact" means a material adverse impact on the regulatory status or the commercial sales of Product.

"MDS" means myelodysplastic syndrome.

"Milestones" means collectively the Development/Regulatory Milestones and the Net Sales Milestones.

"MTAs" means collectively (a) that certain [*], between Licensor and [*], (b) that certain Material Transfer Agreement, dated as of [*], between [*], (c) that certain Materials Transfer Agreement, dated [*], between Licensor and [*], and (d) such other similar agreements that may exist or be entered into from time to time.

"Net Sales" means, with respect to any Product, the total amount invoiced by Licensee or its Affiliates or Sublicensees (each, a "Selling Party") to each Third Party receiving such Product in arm's length transactions, less the following deductions from such total amounts that are actually incurred, allowed, accrued or specifically allocated, each as calculated in accordance with GAAP:

(a) normal and customary trade, cash and quantity discounts (and including amounts repaid, discounted or credited by reason of risk sharing schemes with any Governmental Authority or any Non-Governmental Authority), actually given, credits, price adjustments or allowances for damaged Product, delayed ship orders, returns or rejections of Product, including recalls and allowances for uncollectible amounts, bad debts, or both on previously sold Products;

(b) chargeback payments and rebates (or the equivalent thereof) (including amounts repaid, discounted or credited by reason of retroactive price reductions, discounts, or rebates, which are, in each case, imposed upon the Selling Party by any Governmental Authority or any non-Governmental Authority) and other payments required by law to be made under Medicaid, Medicare and other government special medical assistance programs, branded prescription drug fees (or similar taxes, charges, fees, duties, levies or other assessments) due under the Affordable Care Act (or similar legislation), for Product granted to group purchasing organizations, managed healthcare organizations or to federal, state/provincial, local and other governments, including their agencies, purchasers, reimbursers, non-Governmental Authorities, or to trade customers;

(c) reasonable and customary freight, shipping insurance and other transportation expenses directly related to the sale of Product (if actually borne by the Selling Party without reimbursement from any Third Party);

(d) required distribution commissions/fees payable to any Third Party providing distribution services to Licensee to the extent the amount has been invoiced and actually paid by the Licensee; and

(e) sales, use, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, transportation or delivery of Product (but not including taxes assessed against the income derived from such sale).

In the event that a Product is sold in a given country together with one or more other therapeutically active ingredients or therapies not constituting a Product for a single price (regardless of their packaging) (a "Combination Product"), such Product shall be deemed to be sold in such country for an amount equal to the product of (i) the price at which the Combination Product was sold in such country and (ii) the fraction A/(A+B), where A is the weighted average sale price (by sales volume) in such country during the applicable reporting period of the Product when sold alone, and B is the weighted average sale price (by sales volume) in such country during the applicable reporting period of each other therapeutically active ingredient or therapy included in the Combination Product when sold alone. Regarding prices comprised in the weighted average price when sold separately referred to above, if these are available for different dosages of the Product or other therapeutically active ingredients or therapies than those included in the Combination Product, then Licensee will be entitled to make a proportional adjustment to such prices in calculating the royalty-bearing Net Sales of the Combination Product. If the weighted average sale price cannot be determined for a Product or other therapeutically active ingredients or therapies, the calculation of Net Sales for Combination Products will be agreed by the Parties based on the relative fair market value contributed by each component (each Party's agreement not to be unreasonably withheld, conditioned or delayed).

Upon the sale or other disposal of Product other than in a transaction generating revenues from or based on a sales price for Product (which sales price is either customary or would be reasonably expected), such sale or disposal will constitute a sale with the consideration for the sale being the consideration for the relevant transaction and will constitute Net Sales hereunder or if the consideration is not a monetary amount, such sale or disposal will have the value of whatever consideration has been provided in exchange for the supply. A qualifying amount may be deducted only once regardless of the number of the preceding categories that describe such amount. If a Selling Party makes any adjustment to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments and payment of any royalties due will be reported with a subsequent quarterly report.

For this definition:

(x) the transfer of Product by a Selling Party to Licensee or its Affiliates or sublicensees is not considered a sale;

(y) the transfer of Product by a Selling Party to a contract manufacturer is not considered a sale; and

(z) any disposal of Product for, or use of Product in, non-Clinical Studies, Clinical Studies or as free samples is not a sale under this definition.

For clarity, there is no limit on the quantity of Product that may be used in Clinical Studies. Free samples are permitted within customary limits. The amount of Product transferred pursuant to subsections (x), (y) and (z) of this definition is determined from the books and records of the Selling Party, maintained in accordance with GAAP, but excluding any notes thereto.

"Net Sales Milestones" has the meaning set forth in Section 8.2(b).

"Non-Breaching Party" has the meaning set forth in Section 13.3(a).

"Non-Governmental Authority" means any public body (including the National Institute of Clinical Excellence and the Scottish Medicines Consortium in the United Kingdom; the Institute for Quality and Efficiency in Healthcare in Germany; the Technical Scientific Commission in Italy; the Directorate of Pharmacy and Healthcare Products in Spain; the National Union of Health Insurance Funds and the National Authority of Health in France; and Health Canada in Canada) or non-Governmental Authority (including "Sick Funds" in Germany) with the authority to control, approve, recommend or otherwise determine pricing and reimbursement of pharmaceutical products, including those with authority to enter into risk sharing schemes or to impose retroactive price reductions, discounts, or rebates.

"Oncology Field" has the meaning set forth in Section 4.1.

"Paragraph IV Notice" has the meaning set forth in Section 9.4(f).

"Party" or "Parties" has the meaning set forth in the Preamble.

"Patents" means (a) pending patent applications, issued patents, utility models and designs anywhere in the world; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) any other patent application claiming priority to any of the foregoing anywhere in the world; and (d) extension, renewal or restoration of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

"Payee" has the meaning set forth in Section 8.6.

"PDF" means Adobe™ Portable Document Format sent by electronic mail.

"Phase 1 Study" means a human clinical trial with the endpoint of determining initial tolerance, safety or pharmacokinetic information in single dose, single ascending dose, multiple dose or multiple ascending dose regimens, as described in 21 C.F.R. § 312.21(a) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"Phase 2 Study" means a human clinical trial with the principal purpose being a preliminary determination of safety and efficacy in the target patient population over a range of doses and dose

regimens, as described in 21 C.F.R. § 312.21(b) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"Phase 3 Study" means a human clinical trial of a compound or product for an indication on a sufficient number of subjects that is designed to establish that such compound or product is safe and efficacious for its intended use, and to determine warnings, precautions and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support regulatory approval of such compound or product for such indication or label expansion of such compound or product.

"Phase 3 Study Approval" has the meaning set forth in Section 4.3(a)(i).

"Pricing and Reimbursement Approval" means (a) the governmental approval, agreement, determination or decision establishing prices for a Product that can be charged in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price of pharmaceutical products, and (b) the approval, agreement, determination or decision recommending or approving a Product for use or establishing the prices for a Product that can be reimbursed in regulatory jurisdictions where the applicable Governmental Authority or Non-Governmental Authority approves, determines or recommends the reimbursement or use of pharmaceutical products; *provided*, that in all cases Pricing and Reimbursement Approval shall only be deemed obtained after Drug Approval has been obtained in the applicable jurisdiction.

"Product" means any pharmaceutical product preparation (including any and all forms, presentations, dosages, and formulations) for use for any and all Indications in the Field containing CX-01, any salt, solvate, hydrate, polymorph or co-crystal of CX-01, or any improvement or variation made by Licensor or Licensee to CX-01, in any mode of administration, alone or in combination with any other active agent, including any new dosage strengths, presentations, formulations, methods of administration and line extensions developed by Licensor or Licensee pursuant to the terms of this Agreement.

"Publication" has the meaning set forth in Section 12.3.

"Pyramid Agreement" means that certain Master Service Agreement, dated as of August 14, 2015, between Pyramid Laboratories Inc. and Licensor.

"Reference Product" has the meaning set forth in the definition of Generic Product.

"Regulatory Approval" means (a) Drug Approval and all other approvals necessary for the commercial sale of a Product in a given country or regulatory jurisdiction without any post-marketing commitments; and (b) Pricing and Reimbursement Approval (but only in those countries or regulatory jurisdictions where Pricing and Reimbursement Approval is required by Law for commercial sale).

"Regulatory Authority" means, in a particular country or jurisdiction, any applicable Governmental Authority or Non-Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

"Regulatory Exclusivity" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or jurisdiction in the Territory, other than a Patent, that limits or prohibits a Person from [*].

"Regulatory Materials" means regulatory applications, submissions, notifications, communications, correspondence, registrations, INDs, Drug Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to research, Develop, manufacture, market, sell or otherwise Commercialize any Product in a particular country or jurisdiction.

"Regulatory Plan" has the meaning set forth in the definition of Development Plan.

"Royalty Term" has the meaning set forth in Section 0.

"SEC" has the meaning set forth in Section 12.4(d).

"Section 365(n)" means Section 365(n) of the Bankruptcy Code or analogous provisions of the bankruptcy laws of any Governmental Authority.

"Selling Party" has the meaning set forth in the definition of Net Sales.

"Sublicensee" means any entity, other than an Affiliate of Licensee, to whom Licensee assigns, grants, conveys, licenses, or transfers any rights to research, Develop, Commercialize, manufacture or otherwise exploit a Product, including any sublicense validly granted pursuant to Section 2.1(b).

"Supply Agreement" means that certain Supply Agreement, dated as of October 5, 2015, between Licensor and Scientific Protein Laboratories LLC.

"Term" has the meaning set forth in Section 13.1.

"Territory" means all countries and territories in the world.

"Territory Infringement" has the meaning set forth in Section 9.4(a).

"Third Party" means any entity other than Licensor or Licensee or an Affiliate of either of them or any contract manufacturer.

"Third Party Patent Claim" has the meaning set forth in Section 0.

"Treatment" has the meaning set forth in Section 4.1.

"U.S." means the United States of America, including all possessions and territories thereof.

"Valid Claim" means a pending claim or claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (a) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (b) a holding, finding or decision of invalidity,

unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal (other than a petition to the United States Supreme Court for a writ of certiorari), *provided* that if any such pending claim does not issue within three (3) years from its earliest priority date, such pending claim will cease to be a Valid Claim unless and until actually issued.

ARTICLE 2

LICENSES

2.1 License to Licensee.

(a) License Grant to Licensee. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (even as to Licensor) license, with the right to grant sublicenses as permitted under Section 2.1(b), under the Licensor Technology (including any Licensor Inventions), to research, Develop, make, have made, register, use, sell, offer for sale, import and export and otherwise Commercialize Products in the Field in the Territory.

(b) Sublicense Rights. Licensee may grant sublicenses through multiple tiers (i) of the licenses granted in Section 2.1(a), or (ii) of any rights to distribute and/or sell any Product in the Field in the Territory, to any Affiliate or Third Party without the approval of Licensor unless such sublicense constitutes an exclusive grant to a Third Party of Licensee's rights to Develop and Commercialize a Product in a Major Market Country, in which case such sublicense shall require the prior written approval of Licensor, which approval will not be unreasonably withheld, conditioned or delayed; *provided* that in all events (1) Licensee shall remain responsible for the performance of its Sublicensees hereunder and must not grant any rights that are inconsistent with the rights granted to and obligations of Licensee hereunder; and (2) Licensee shall, upon Licensor's written request, provide Licensor with a copy of each sublicense agreement for its Sublicensees (for the avoidance of doubt, excluding any sublicense agreement with any Affiliate of Licensee), which may be reasonably redacted to exclude Sublicensee proprietary information, within thirty (30) days of execution, which copy shall be treated as Confidential Information of Licensee hereunder.

2.2 License to Licensor. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Licensor a non-exclusive license, under the Licensee Technology and the Licensor Technology, to Develop Products solely in accordance with, and solely for the purposes of, performing Licensor's obligations under Section 4.3(a).

2.3 Negative Covenants.

(a) Licensee will not, and will not permit any of its Affiliates or Sublicensees to, use or practice any Licensor Technology outside the scope of the licenses granted to it under Section 2.1.

(b) Licensor will not, and will not permit any of its Affiliates or licensees to, use or practice any Licensee Technology or Licensor Technology outside the scope of the licenses granted to it under Section 2.2.

2.4 Exclusivity Covenant. The Parties, their Affiliates, and their respective sublicensees will not, directly or through any Third Party, other than pursuant to this Agreement, develop, register, manufacture, have manufactured, import, export, market, distribute or sell in the Territory any Competitive Products until the [*] of the termination of this Agreement. For clarity, the provisions of this Section 2.4 shall continue to apply with respect to those jurisdictions where this Agreement remains in effect in the event of a partial termination of this Agreement. Notwithstanding the foregoing, in the event of a Change of Control of a Party, nothing in this Section 2.4 shall be construed to limit or restrict the activities or operations of the Acquiror or its Affiliates (other than the acquired Party and the pre-acquisition Affiliates of the acquired Party).

2.5 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party will be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

ARTICLE 3

GOVERNANCE

3.1 Joint Development Committee.

(a) Formation and Role. Within thirty (30) days after the Effective Date, the Parties will establish a joint development committee (the "JDC") for the overall coordination and oversight of the Parties' activities under this Agreement. The role of the JDC is:

(i) to review, discuss and approve the overall strategy for the Development and Regulatory Approval of Products in the Field in the Territory;

(ii) to review and discuss the overall performance of the Parties pursuant to this Agreement and to compare such performance to the objectives outlined in the Development Plan and to the diligence obligations set forth in Section 4.3;

(iii) to review, discuss and approve any amendments to the Development Plan (including the Regulatory Plan);

(iv) to perform such other functions as appropriate to further the purposes of this Agreement as expressly set forth in this Agreement or as mutually determined by the Parties in writing.

The JDC has only the powers expressly assigned to it in this Section 3.1 and elsewhere in this Agreement. The JDC has no power to interpret, amend, modify, or waive compliance with this Agreement.

(b) Members. Each Party will initially appoint two (2) representatives to the JDC, each of whom will be an officer or employee of such Party having sufficient seniority within the applicable Party to make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of its members and each Party may replace its representatives at any time upon written notice to the other Party; *provided*, *however*, that the JDC will at all times consist of an equal number of members appointed by each Party. If a JDC representative from either Party is unable to attend or participate in a meeting of the JDC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting. The JDC will have a chairperson, who will be elected, on an annual basis, alternately by Licensor or Licensee. The Licensee will elect the initial chairperson. The role of the chairperson is to convene and preside at all meetings of the JDC and to ensure the preparation of meeting minutes, but the chairperson has no additional powers or rights beyond those held by other JDC representatives.

(c) Meetings. The JDC will meet at least one (1) time per Calendar Quarter until the date on which there are no further Development activities ongoing in respect of the Product. Either Party may also call a special meeting of the JDC (including by videoconference or teleconference) upon at least ten (10) Business Days' prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled meeting, and such Party will provide the JDC no later than ten (10) Business Days before the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JDC may meet in person, by videoconference or by teleconference, *provided*, *however*, at least two (2) meetings per Calendar Year occur in person at a mutually agreeable location or alternating each meeting between (i) Durham, North Carolina, and (ii) Miami, Florida or Weston, Florida. Each Party will pay for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JDC meetings as non-voting observers or presenters. The chairperson of the JDC will prepare reasonably detailed written minutes of all JDC meetings that reflect and include all material decisions made at such meetings. The JDC chairperson will send draft meeting minutes to each member of the JDC for review and approval within ten (10) Business Days after each JDC meeting. Such minutes will be approved unless one or more members of the JDC object to the accuracy of such minutes within ten (10) Business Days of receipt.

(d) Decision Making. Actions to be taken by the JDC will be taken only following unanimous vote, with each Party having one (1) vote representing the views of its members. If the JDC fails to reach unanimous agreement on a matter before it for decision for a period in excess of ten (10) Business Days, then either Party may at any time thereafter provide the other written notice specifying the terms of such dispute in reasonable detail and the chief executive officers of each Party shall meet at a mutually agreed upon time and location for the purpose of resolving such dispute. If they are not able to resolve such dispute in a mutually agreeable manner, then the President of Licensee (or his or her designee) may cast the deciding vote for the JDC. Each Party retains the rights, powers, and discretion granted to it under this Agreement and neither Party will delegate to or vest in any such rights, powers, or discretion in the JDC, unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

3.2 Alliance Manager.

(a) Appointment. Within thirty (30) days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative of such Party having a general understanding of pharmaceutical development and commercialization issues sufficient to act as its alliance manager under this Agreement (each an "Alliance Manager"). Each Party may replace its Alliance Manager at any time by written notice to the other Party.

(b) Specific Responsibilities. The Alliance Managers will serve as the primary administrative contact point between the Parties for the activities under this Agreement for the purpose of providing each Party with information on the Development and Regulatory Approval of each Product in the Field in the Territory and shall have the following responsibilities:

(i) facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;

(ii) coordinate the various functional representatives of each Party, as appropriate, in developing and executing strategies and plans;

(iii) assist the integration of teams across functional areas;

(iv) assist the JDC in identifying and raising cross-Party or cross-functional disputes in a timely manner; and

(v) perform such other functions as agreed by the Parties.

3.3 Good Faith. In conducting themselves as a member of the JDC or as an Alliance Manager, all representatives of both Parties will consider diligently, reasonably and in good faith all input received from the other Party, and will try to reach consensus on all matters before them. In exercising any decision-making authority granted to it under this ARTICLE 3, each Party will conduct its discussions in good faith with a view toward operating for the mutual benefit of the Parties and in furtherance of the successful collaboration, Development and Commercialization of Products in the Territory. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of their respective Affiliates will be required to take, or will be penalized for not taking, any action that is not in compliance with such Party's ethical business practices and policies or that such Party reasonably believes is not in compliance with Laws.

3.4 Scope of Governance. The Parties agree not to share or discuss any Confidential Information beyond the scope of the collaboration contemplated by this Agreement. Each Party acknowledges and agrees that the JDC members and participants will receive Confidential Information in connection with JDC meetings. Each Party will ensure that its JDC members and other participants are informed that they should regard all JDC-related information as Confidential Information.

ARTICLE 4

PRODUCT DEVELOPMENT

4.1 Overview. The Parties desire and intend to collaborate with respect to the Development of Products, with an emphasis on Products for the treatment, control, mitigation, prevention, cure or diagnosis (collectively, "Treatment") of oncology Indications (the "Oncology Field"), as and to the extent set forth in this Agreement. As between the Parties, and subject to Licensor's rights at the JDC in accordance with ARTICLE 3, Licensee will be responsible for all aspects of the Development of Products. Notwithstanding the foregoing, the Parties agree that Licensor will be responsible for preparing and delivering to Licensee, in a reasonably organized and readable format standard for a final Clinical Study report, the complete results and data from the Phase 2 Study titled "A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia" when available after the Effective Date. Licensee will bear all of the costs and expenses incurred in connection with all Development activities.

4.2 Development Plan.

(a) Initial Development Plan. Following the Effective Date, the Parties will use their respective reasonable best efforts to negotiate and finalize an initial Development Plan in respect of the Oncology Field as promptly as practicable, and in any event, within sixty (60) days following the Effective Date.

(b) Amendments. The JDC will periodically review, and, as required, prepare amendments to the Development Plan, for review and comment by the Parties. Such proposed amended Development Plan will reflect any changes (including additions) to the Development of Products in the Field in the Territory. Once approved by the JDC, the amended Development Plan will become effective and supersede the previous Development Plan as of the date agreed to in writing by the Parties. Amendments to the Development Plan will only be effective if made pursuant to this Section 4.2(b).

4.3 Diligence.

(a) Licensee's Obligations. Licensee shall use Commercially Reasonable Efforts to Develop at least one Product in each of the [*] in accordance with the Development Plan. Without limitation of the foregoing, Licensee shall use Commercially Reasonable Efforts to adhere to the following timelines:

(i) Within twelve (12) months after [*];

(ii) Within twenty-four (24) months after the [*];

(iii) Within nine (9) months from the delivery of the [*].

(b) Licensor's Obligations. In the event that any Development activities are allocated to Licensor in the Development Plan, Licensor shall conduct such activities using Commercially Reasonable Efforts, in a timely and efficient manner, and in all cases in accordance with the timelines set forth in the Development Plan.

4.4 Data Exchange and Use. Subject to the terms and conditions of this Agreement, (a) Licensor will promptly provide to Licensee (i) all Information obtained by Licensor or any of its licensees related to Products and (ii) all safety data related to Licensor's programs unrelated to the foregoing, and (b) Licensor will cooperate in good faith to provide Licensee access to and reasonable assistance with all Licensor Technology and other Confidential Information as may be required for Licensee to exercise the rights and licenses explicitly granted and to perform its obligations hereunder.

4.5 Compliance with Laws. Each Party will conduct its activities under this Agreement in a good scientific manner and comply in all material respects with all Laws, including applicable national and international guidelines such as ICH, GCP and GLP.

ARTICLE 5

REGULATORY MATTERS

5.1 Regulatory Responsibilities.

(a) Licensee will be responsible for all regulatory submissions and will control all regulatory activities with respect to Products in the Territory, including safety reporting, analysis and strategy. Licensor will provide timely support to Licensee with respect to such regulatory activities at Licensee's cost (other than minor consultation, clerical assistance and other assistance resulting in immaterial expenses, which shall be the responsibility of Licensor) and will, at Licensee's request, promptly transfer all Regulatory Materials and Information in its possession or under its Control related to CX-01 or any Product to Licensee.

(b) Licensee will be the primary interface with and will otherwise handle all correspondence, meetings and other interactions with the relevant Regulatory Authorities concerning regulatory activities related to Products in the Field in the Territory, and Licensee will prepare and file any and all Regulatory Materials for each Product in the Field in the Territory at its sole expense in accordance with the Regulatory Plan. Licensor will assist and cooperate, at Licensee's expense, with Licensee in connection with the preparation and filing of such Regulatory Materials, as reasonably requested by Licensee. Such cooperation will include promptly responding within procedural timelines set by Regulatory Authorities to any reasonable request from Licensee for Licensor Know-How needed for the Regulatory Materials.

(c) Unless the Parties otherwise agree in writing: (i) except as expressly contemplated by this Section 5.1, Licensor will not communicate with respect to any Product in the Field with any Regulatory Authority having jurisdiction in the Territory, unless so ordered by such Regulatory Authority, in which case Licensor will provide prompt (but in any event within 2 business days) notice to Licensee of such order and all details thereof; and (ii) except as expressly contemplated by this Section 5.1, Licensor will not submit any Regulatory Materials or seek Regulatory Approvals for any Product in the Field in the Territory.

(d) Licensee shall provide Licensor with reasonable advance notice of any scheduled significant meeting with the FDA or EMA relating to any Regulatory Approval for a

Product, and Dr. Stephen Marcus, as a representative of Licensor (or a reasonably acceptable replacement if Dr. Marcus is not available), shall, to the extent permitted by the FDA or EMA, as applicable, have the right to attend any such meeting at Licensor's expense. Licensee shall promptly inform (including by providing redacted copies upon request) Licensor about any significant interaction (oral or written) with a Regulatory Authority.

5.2 Regulatory Costs. Licensee will pay for all of its costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for each Product in the Field in the Territory.

5.3 Regulatory Materials. During the Term, Licensor will provide Licensee with access, free of charge, to all Licensor Know-How then in existence and in Licensor's possession that constitutes pre-clinical or clinical data, CMC Information and manufacturing data relating to any Product. Licensor will support Licensee, as reasonably requested by Licensee and at Licensee's cost (other than minor consultation, clerical assistance and other assistance resulting in immaterial expenses, which shall be the responsibility of Licensor), in obtaining Regulatory Approvals in the Territory, including providing necessary documents or other materials required by Laws to obtain Regulatory Approval in the Territory, all in accordance with the terms and conditions of this Agreement.

5.4 No Harmful Actions. If Licensee reasonably believes that Licensor is taking or intends to take any action with respect to any Product that is substantially likely to have a Material Impact upon the Development or regulatory status of any Product in the Territory, Licensee may bring the matter to the attention of the JDC. Except as required by applicable Laws, Licensor will not proceed with any such action or alternative course of action until it is approved by the JDC in accordance with Section 3.1(d).

5.5 Notification of Threatened Action. Each Party will immediately, but in no event later than ten (10) days after receipt, notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may affect the Development or regulatory status of any Product. Upon receipt of such information, the Parties will consult with each other to arrive at a mutually acceptable procedure for taking appropriate action.

ARTICLE 6

MANUFACTURE AND SUPPLY

6.1 Supply. Licensor shall assign, grant, convey and transfer to Licensee all of the rights, title and interests of Licensor in and to the Supply Agreement and the Pyramid Agreement effective as of the Effective Date. In furtherance thereof, concurrently with the execution and delivery of this Agreement, Licensor shall deliver to Licensee, in respect of each of such agreements, an appropriate assignment and consent form duly executed by all parties to the applicable agreement. In addition, Licensor will, promptly after the Effective Date, transfer at no additional cost to Licensee (other than for mutually agreed upon, actual out-of-pocket costs for full time equivalent (FTE) resources from Licensor's contract manufacturing organization to transfer manufacturing

technology), Licensor's (i) existing CX-01 inventory of GMP and non-GMP bulk active pharmaceutical ingredient and bulk drug product, such transfer to be accompanied by appropriate representations, warranties, covenants and conditions as to GMP compliance, and (ii) the manufacturing technology developed by Licensor to date and controlled by Licensor with respect to the manufacture of CX-01.

ARTICLE 7

COMMERCIALIZATION

7.1 Overview. Subject to the terms and conditions of this Article 7, as between the Parties, Licensee will be responsible for all aspects of the Commercialization of Products in the Field in the Territory. Licensee will bear all of the costs and expenses incurred in connection with such Commercialization activities.

7.2 Diligence. Upon obtaining Regulatory Approval of a Product in a Major Market Country, Licensee will use Commercially Reasonable Efforts to Commercialize such Product in the approved Indication in such Major Market Country, with Licensor's timely assistance, if reasonably requested by Licensee and at Licensee's sole cost. Notwithstanding anything herein to the contrary, Licensee's commitment to use Commercially Reasonable Efforts as set forth herein shall not preclude the suspension or discontinuance of the Development or Commercialization of any Product, if appropriate, based on the application of Commercially Reasonable Efforts. Licensor hereby acknowledges and agrees that Licensee and its Affiliates make (and have made) no representation or warranty, either express or implied, at law or in equity, that it will be able to successfully achieve the Milestones, or that it will be able to achieve any amount of Net Sales, and Licensor specifically disclaims that it is relying upon or has relied upon any such representations or warranties that may have been made by any individual or entity. Except as set forth in Section 2.4, nothing in this Agreement shall limit or restrict the right of Licensee or its Affiliates to Develop, make regulatory filings, obtain Regulatory Approvals with respect to, or Commercialize any product or to engage in any business or other activity.

7.3 Pricing. Licensee will determine all pricing of Products in the Field in the Territory. For the avoidance of doubt, Licensor does not have any right to direct, control, or approve Licensee's pricing of Products in the Field in the Territory.

ARTICLE 8

COMPENSATION

8.1 Upfront Payment.

(a) Cash Consideration. In consideration of the rights granted to Licensee herein, Licensee will pay to Licensor a one-time, non-refundable, upfront fee of Thirty Million Dollars ($30,000,000) within five (5) Business Days following the Effective Date.

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

(b) Equity Consideration. In consideration of the rights granted to Licensee herein, Licensee will issue to Licensor, within five (5) Business Days following the Effective Date, ten million (10,000,000) shares (the "Shares") of Licensee's common stock, par value $0.001 per share (the "Common Stock"). The Shares shall be subject to a one-year lock up and Licensor shall be entitled to registration rights with respect to such Shares, all as set forth in the form agreement attached to this Agreement as Exhibit A (the "Lock Up Agreement").

8.2 Milestone Payments.

(a) Development/Regulatory Milestone Payments. In addition to the payment set forth in Section 8.1, Licensee will pay the following one-time Development/regulatory milestone payments (the "Development/Regulatory Milestones") to Licensor, each within thirty (30) days after the first achievement of each Development/Regulatory Milestone event indicated below:

	Development/Regulatory Milestone Event	**Milestone Payment**
1.	[*]	$[*]
2.	[*]	$[*]
3.	[*]	$[*]
4.	[*]	$[*]
5.	[*]	$[*]
6.	[*]	$[*]
7.	[*]	$[*]

The Development/Regulatory Milestone payments set forth in this Section 8.2(a) are payable only once, the first time the Development/Regulatory Milestone event is achieved. For clarity, this means that the total maximum amount of Development/Regulatory Milestone payments payable under this Section 8.2(a) is $202,500,000.

(b) Net Sales Milestone Payments. In addition to the payment set forth in Section 8.1, Licensee will make the following, one-time milestone payments (the "Net Sales Milestones") to Licensor when the aggregate Net Sales of all Products in the Territory first reach the specified amount listed in the "Net Sales Milestone Event" column below in any Calendar Year:

	Net Sales Milestone Event	Milestone Payment
1.	Net Sales of Products in a Calendar Year in the Territory exceed One Hundred Million Dollars ($100,000,000)	$[*]
2.	Net Sales of Products in a Calendar Year in the Territory exceed Two Hundred Fifty Million Dollars ($250,000,000)	$[*]
3.	Net Sales of Products in a Calendar Year in the Territory exceed Five Hundred Million Dollars ($500,000,000)	$[*]
4.	Net Sales of Products in a Calendar Year in the Territory exceed One Billion Dollars ($1,000,000,000)	$[*]
5.	Net Sales of Products in a Calendar Year in the Territory exceed Two Billion Dollars ($2,000,000,000)	$[*]

Each Net Sales Milestone in this Section 8.2(b) is separate and will be paid only once, the first time the Net Sales Milestone event is achieved. The maximum amount payable to Licensor pursuant to this Section 8.2(b) will be $385,000,000. Licensee will notify Licensor in writing within thirty (30) days after the end of the Calendar Quarter in which the applicable Net Sales Milestone Event is achieved and payment shall accompany such report.

8.3 Royalties.

(a) Royalty Rates. Licensee will pay to Licensor royalties on Net Sales of all Products in the Territory during the Royalty Term, as calculated by multiplying the applicable royalty rate set forth below (subject to reductions as set forth herein) by the corresponding amount of incremental, aggregated Net Sales of all Products in the Territory in such Calendar Year.

Annual Net Sales of all Products in the Territory	Royalty Rate
For that portion of annual Net Sales less than or equal to [*]	[*]%
For that portion of annual Net Sales greater than [*] but less than [*]	[*]%
For that portion of annual Net Sales equal to or greater than [*] but less than [*]	[*]%
For that portion of annual Net Sales equal to or greater than [*] less than [*]	[*]%
For that portion of annual Net Sales equal to or greater than [*]	[*]%

(b) Royalty Term. Licensee will pay to Licensor royalties on Net Sales of Products under this Section 8.3 on a country-by-country basis, during the period in which [*] (the

"Royalty Term"). Upon the expiry of the Royalty Term in a given country, the license granted to Licensee pursuant to Section 2.1(a) will become a fully paid-up and royalty-free license for that country.

(c) Royalty Reduction During Market Exclusivity. During the period of the Royalty Term where only Market Exclusivity remains, on a country-by-country and Product-by-Product basis, the royalty rates payable on Net Sales of such Product within such country of the Territory shall be reduced by [*].

(d) Royalty Reduction for Third Party License. If Licensee reasonably determines it is necessary to seek or obtain a license from any Third Party to Develop or Commercialize a Product in any country in the Territory, then Licensee may offset against royalties otherwise due to Licensor under this Agreement with respect to such country an amount equal to [*] of any royalties or other license fees/payments actually paid by Licensee to such Third Party under such license; *provided* that in no event will the royalties payable by Licensee in any Calendar Quarter with respect to any country be reduced by more than [*] as a result of this Section 8.3(d). Notwithstanding the foregoing, any excess amounts that would have otherwise been deducted in such Calendar Quarter pursuant to this Section 8.3(d) shall be deducted from royalties otherwise due to Licensor under this Agreement with respect to such country in successive Calendar Quarters until the credit has been realized in full.

(e) Royalty Reports and Payments. Within thirty (30) days following the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale of Product is made anywhere in the Territory, Licensee shall provide Licensor with a report containing the following information for such Calendar Quarter, on a country-by-country basis: (i) the amount of gross sales of Product in the Territory, (ii) an itemized calculation of Net Sales in the Territory showing deductions provided for in the definition of "Net Sales" and any rebates that are known to be required in respect of the Calendar Quarter in question, (iii) the conversion of such Net Sales from the currency of sale into Dollars, and (iv) the calculation of the royalty payment due on such sales, showing the application of the reduction, if any, made in accordance with the terms of Section 8.3(d). If and to the extent that Licensee identifies an error in a prior royalty report, it shall set forth the error and related calculations in the current royalty report. Concurrent with the delivery of the applicable quarterly report, Licensee shall pay in Dollars all amounts due (adjusted to correct any errors in a prior report) to Licensor pursuant to this Section 8.3 with respect to Net Sales by Licensee, its Affiliates and their respective Sublicensees for such Calendar Quarter.

8.4 Blocked Currency. In each country in the Territory where the local currency is blocked and cannot be removed from the country, Licensee will pay to Licensor royalties accrued on Net Sales in such country in the equivalent amount in Dollars.

8.5 Foreign Exchange. Conversion of sales recorded in local currencies to Dollars will be calculated, on a quarterly basis, using the average daily closing rate of exchange for Calendar Quarter as reported in the Financial Times (London edition) in the Calendar Quarter before the date of payment.

8.6 Payment Method; Late Payments. Each Party will make all payments due hereunder in Dollars by wire transfer of immediately available funds into an account designated by the Party that is owed such payment (such Party, the "Payee"). If the Payee does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to the Payee until the date of payment at the per annum rate of the then-current prime rate as reported in The Wall Street Journal plus [*], or the maximum rate allowable by Laws, whichever is lower. Notwithstanding the foregoing, a Party making a payment pursuant to this Agreement shall not be deemed to have made a late payment, and no interest shall be due pursuant to this Section 8.6, if the payment is not made by the due date as a result of the Payee's efforts to reduce or eliminate a tax applicable to such payment pursuant to Section 8.9(c) solely upon and pursuant to the request of the other Party, *provided* the paying Party makes the required payment (net of applicable withholding taxes) as soon as practicable after the tax issue is resolved.

8.7 Records. Each Party will keep (and will ensure that its Affiliates and sublicensees keep) such records as are required to determine, in accordance with GAAP or international financial reporting standards, as applicable, and this Agreement, the sums or credits due under this Agreement, including Net Sales. Each Party will retain all such books, records and accounts until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Laws. Each Party will require its sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such sublicensee, which report will be made available to the other Party in connection with any audit conducted by such other Party pursuant to Section 8.8.

8.8 Audits. Each Party may have an independent regional or national certified public accounting firm, reasonably acceptable to the audited Party, have access during normal business hours, and upon reasonable prior written notice, to examine only those records of the audited Party (and its Affiliates and sublicensees) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than three (3) years before such Party's request, the correctness or completeness of any report or payment made under this Agreement; *provided*, *however*, the audited Party shall not be required to provide, and neither the auditing Party nor the independent certified public accountant engaged by the auditing Party shall be entitled to review, the tax returns or tax records of the audited Party or those of its Affiliates and sublicensees. The foregoing right of review may be exercised only once per year and only once with respect to each such periodic report and payment. Reports of the results of any such examination will be (a) limited to details of any discrepancies in the audited Party's records relating to Product together with an explanation of the discrepancy and the circumstances giving rise to the discrepancy (b) made available to both Parties and (c) subject to Article 12. If the audit report concludes that (i) additional amounts were owed by the audited Party, the audited Party will pay the additional amounts, with interest from the date originally due as provided in Section 8.6 or (ii) excess payments were made by the audited Party, the auditing Party will reimburse such excess payments, without interest, in either case ((i) or (ii)), within thirty (30) days after the date on which such audit report is delivered to both Parties. The Party requesting the audit will bear the full cost of the performance of any such audit, unless such audit, which covers the entire Calendar Year, discloses a variance to the detriment of the auditing Party of more than [*] from the amount of the original report, royalty or payment

calculation, in which case the audited Party will bear the full cost of the performance of such audit. The results of such audit will be final, absent manifest error.

8.9 Taxes.

(a) Taxes on Income. Each Party will pay all taxes (including related interest and penalties) imposed on its share of income arising directly or indirectly from the efforts of, or the accrual, receipt or deemed receipt of any payment by, such Party under this Agreement.

(b) Tax Withholding. If any taxes (including related interest and penalties) are required to be withheld by a Party with respect to an amount payable to the other Party, such Party will: (a) withhold such taxes from the payment made to the other Party; (b) timely pay the withheld taxes to the proper taxing authority; (c) send proof of payment to the other Party; and (d) reasonably assist the other Party in its efforts to obtain a refund of or credit for such tax payment in accordance with Section 8.9(c). Any amount actually withheld and remitted by a Party to a taxing authority pursuant to this Section 8.9(b) will be treated for all purposes of this Agreement as paid to the other Party. If a Party makes a payment without deduction for tax withholding and an amount of tax should have been withheld from such payment, the Party that made such payment shall be entitled to recover the underwithheld tax (and any penalties, additions to tax and interest related thereto and any penalties, additions to tax and interest payable by the paying Party due to the failure to timely withhold) by an additional withholding from any amount payable to the other Party under this Agreement, and to the extent such recovery is insufficient, such Party may make a claim pursuant to ARTICLE 11. No amount shall be withheld, or a reduced amount shall be withheld, as applicable, if, in accordance with Section 8.9(c), a Party that is entitled to a payment timely furnishes the other Party with the necessary tax forms and other documents prescribed by applicable Laws, which shall be in a form reasonably satisfactory to the Party receiving the documents, identifying that the relevant payment is exempt from tax or subject to a reduced tax rate.

(c) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by one Party to the other Party under this Agreement. The Party entitled to a payment will provide the paying Party with any tax forms that may be reasonably necessary in order for the paying Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

ARTICLE 9

INTELLECTUAL PROPERTY MATTERS

9.1 Ownership of Inventions.

(a) General. Licensee will own any Inventions invented (a) solely by its own employees, agents or independent contractors and (b) jointly by employees, agents or independent

contractors of each Party, in the course of conducting the activities under this Agreement, together with all intellectual property rights therein ("Licensee Inventions"). Licensor will own any Inventions invented solely by its own employees, agents or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein ("Licensor Inventions"), all of which, for the avoidance of doubt, constitute Licensor Technology and are included in the license in Section 2.1.

(b) United States Law. The determination of ownership rights of Inventions shall, for the purposes of this Agreement, be made in accordance with applicable Law in the U.S. Each Party shall, and does hereby, assign, and shall cause its Affiliates and their sub(licensees) and Sublicensees to so assign, to the other Party, without additional compensation, all right, title and interest in and to any Information and other Inventions as necessary to fully effect the ownership provided for in Section 9.1(a).

(c) Assignment Obligation. Each Party shall cause all persons who perform Development activities or regulatory activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Inventions by or on behalf of either Party or its Affiliates or its or their (sub)licensees (or Sublicensees) under or in connection with this Agreement to be under an obligation to assign (or, if such Party is unable to cause such person to agree to such assignment obligation despite such party's using commercially reasonable efforts to negotiate such assignment obligation, then to grant an exclusive license under) their rights in any Inventions resulting therefrom to such Party, except where applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain such a license, shall be obtained). In addition, each Party shall require (and shall cause its Affiliates and Sublicensees to require) that any Third Party collaborator assign to such Party all of its rights, title and interest in and to any Inventions so to fully effect the ownership provided for in Section 9.1(a).

9.2 Disclosure of Inventions; Patent Strategy Consultation. Each Party will promptly disclose to the other Party all Inventions (whether Licensor Inventions or Licensee Inventions), including any Invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing Inventions that are either Licensor Inventions or Licensee Inventions, and all material Information relating to such Inventions to the extent necessary or useful for the preparation, filing and maintenance of any Patent, and the determination of inventorship, with respect to such Invention.

9.3 Prosecution of Patents.

(a) Subject to Section 9.3(b), as between the Parties, Licensee may prepare, file, prosecute and maintain the Licensee Patents, the Licensor Patents and any Patent covering Licensor Inventions directed to any Product, including the manufacture or use thereof (collectively, the "Licensee Prosecuted Patents"). As between the Parties, Licensee will bear and be solely responsible for all costs incurred after the Effective Date only in connection with the preparation, filing, prosecution or maintenance of any Licensee Prosecuted Patent that it chooses to prepare, file, prosecute or maintain in the Territory. Before any substantive prosecution filing, Licensee will provide Licensor with a reasonable opportunity to review and comment on such prosecution efforts

regarding the Licensee Prosecuted Patents as follows: Licensee will promptly provide Licensor with copies of all material communications from any patent authority regarding the Licensee Prosecuted Patents, and will provide Licensor, for its review and comment, with drafts of any material filings or responses to be made to such patent authorities in a reasonable amount of time in advance of submitting such filings or responses. Licensee will consider in good faith any reasonable comments thereto provided by Licensor in connection with the prosecution of the Licensee Prosecuted Patents. Each Party will provide the other Party all reasonable assistance and cooperation (at the other Party's cost) in the Patent prosecution efforts provided in this Section 9.3(a), including executing any other required documents or instruments for such filings and prosecution.

(b) If Licensee decides not to prepare or file, or to abandon, any Licensee Prosecuted Patent or not to apply for an extension of any Licensee Prosecuted Patent, including a supplementary protection certificate or equivalent thereof, anywhere in the Territory, Licensee will promptly notify Licensor and Licensor may assume Licensee's rights and responsibilities under this Section 9.3 with respect to such Licensee Prosecuted Patent, and in connection with assuming such rights and responsibilities, including responsibility for costs, Licensor may prepare, file, prosecute, or maintain such Licensee Prosecuted Patent or apply for any extension (including a supplementary protection certificate or equivalent thereof) and Licensor will thereafter control the prosecution and maintenance of such Licensee Prosecuted Patent in the Territory; *provided* that any such Licensee Prosecuted Patent that is a Licensor Patent, shall thereafter be excluded from the definition of "Licensor Patents" for purposes of the license grant in Section 2.1(a).

9.4 Patent Enforcement.

(a) Notification. If either Party becomes aware of any existing or threatened infringement of any of the Licensee Patents or the Licensor Patents in the Field anywhere in the Territory by a Third Party, including any declaratory judgment, and opposition, post-grant administrative proceedings, or similar action from a Third Party alleging the invalidity, unenforceability, or non-infringement of any of the Licensee Patents or Licensor Patents ("Territory Infringement"), such Party will promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Territory Infringement.

(b) Enforcement Rights. For any Territory Infringement, each Party will share with the other Party all Information available to it regarding such actual or alleged infringement. As between the Parties, Licensee may bring an appropriate suit or other action against any person or entity engaged in any such Territory Infringement which infringes any Licensee Patent or any Licensor Patent that includes claims directed to any Product, at Licensee's cost and expense. Licensor will take appropriate action to enable Licensee to commence a suit or take the actions set forth in the preceding sentence. If Licensee fails to commence a suit to enforce the applicable Licensor Patents against such Territory Infringement or to settle or otherwise secure the abatement of such Territory Infringement within one hundred eighty (180) days after becoming aware of such Territory Infringement, then Licensor may commence a suit or take action to enforce such Licensor Patents against such Territory Infringement at its own cost and expense. In this case, Licensee will take

appropriate actions to enable Licensor to commence a suit or take the actions set forth in the preceding sentence.

(c) Collaboration. Each Party will provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including executing all necessary and proper documents and if required to establish and maintain standing to join such action as a party plaintiff if required by Law to pursue such action, *provided* that the Party so joined as a party plaintiff shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to such action, and the enforcing Party agrees to fully indemnify, defend and hold harmless the other Party from and against all Claims (including reasonable legal fees and expenses) incurred by the other Party relating thereto. Each Party will additionally use Commercially Reasonable Efforts to have joined to such action as a party plaintiff any Third Party whose joinder is required by law to establish and maintain standing to pursue such action. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts, will reasonably consider the other Party's comments on any such efforts, and will seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which consent will not be unreasonably withheld, conditioned or delayed. The non-enforcing Party may obtain separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party, subject to the provisions of Section 9.4(d).

(d) Settlement. Licensor will not settle any claim, suit or action that it brought under Section 9.4(b) in any manner that would negatively impact the applicable Licensor Patents or that would limit or restrict the ability of Licensee to Develop, make, have made or Commercialize Products anywhere in the Territory in the Field, without the prior written consent of Licensee, which consent will not be unreasonably withheld, conditioned or delayed. Nothing in this Article 9 requires Licensee to consent to any settlement that is reasonably anticipated by Licensee to have a substantially adverse impact upon any Licensor Patent in the Territory, or to the Development, manufacture or Commercialization of Products in the Territory in the Field. Licensee will not settle any Territory Infringement Action that (i) includes any statement that may be used as an admission of invalidity or unenforceability of any Licensor Patents, or (ii) imposes any material obligations on Licensor, or admits fault on behalf of Licensor, in each case without Licensor's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

(e) Expenses and Recoveries. The enforcing Party bringing a claim, suit, or action under Section 9.4(b) will pay for any expenses incurred by such Party as a result of such claim, suit, or action. If such Party recovers monetary damages in such claim, suit or action, such recovery will be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts will be retained as follows: (i) if Licensee is the enforcing Party, then the remaining amount attributable to a recovery for lost sales or profits shall be deemed "Net Sales" in the Calendar Year in which the money is actually received, and Licensee shall pay the corresponding royalty on such amount to Licensor in accordance with Section 8.3, and (ii) if Licensor is the enforcing Party, then Licensor shall retain [*] of such remaining amount and shall pay [*] to Licensee.

(f) Hatch Waxman Litigation. Notwithstanding anything herein to the contrary, should a Party receive a certification under 21 U.S.C. § 355 (j)(2)(A)(vii)(iv) and 21 C.F.R. § 314.94 (a)(12)(i)(A)(4) with respect to one or more Licensor Patents or Licensee Patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, known as the Hatch-Waxman Act), as amended, or its equivalent in a country other than the US, then such Party shall immediately provide the other Party with a copy of such certification. Licensee shall have ten (10) Business Days from date on which it receives or provides a copy of such certification to provide written notice to Licensor ("Paragraph IV Notice") whether Licensee will bring suit, at its expense, within a forty-five (45) day period from the date of such certification. Should such ten (10) Business Day period expire without Licensee providing such Paragraph IV Notice to Licensor or with written notification that Licensee has no intention to bring suit under the Hatch-Waxman Act, then Licensor shall be free to immediately bring suit in its name.

9.5 Infringement of Third Party Rights. If a Product made, used, offered for sale or sold by Licensee, its Affiliates or Sublicensees, the Licensor Technology and/or the Licensee Technology becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory (each such claim or assertion a "Third Party Patent Claim"), Licensee will promptly notify Licensor and the Parties will work toward their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties will promptly meet to consider the Third Party Patent Claim and the appropriate course of action. Licensee will defend any such Third Party Patent Claim that pertains solely to patents that include claims directed to any Product; *provided* that the provisions of Section 9.4 govern the right of Licensee to assert a counterclaim of infringement of any Licensee Patent or any Licensor Patents. Notwithstanding the above, Licensee shall not enter into any settlement of any Third Party Patent Claim without the prior written consent of Licensor if such settlement would require the Licensor to be subject to an injunction or to make any monetary payment to the Licensee or Third Party, or admit any wrongful conduct Licensor or its Affiliates, or would limit or restrict the claims of or admit any invalidity and/or unenforceability of any of the Licensor Patents, without Licensor's prior written consent, which shall not be unreasonably withheld.

9.6 Patent Marking. Licensee and its Affiliates and Sublicensees will mark any Product marketed and sold by Licensee or its Affiliates or Sublicensees hereunder with appropriate patent numbers or indicia; *provided*, *however*, that Licensee will only be required to so mark such Product (a) to the extent such markings or such notices would affect recoveries of damages or equitable remedies available under Laws with respect to infringement of Patents in the Territory or (b) as otherwise required by applicable Law.

9.7 Packaging; Trademarks. Licensee will design all final commercial packaging and labeling of Product for use in the Territory, and may select the brand name of Products in the Territory and register any trademarks resulting therefrom at Licensee's sole cost and expense.

9.8 Common Interest Agreement. To the extent necessary or advisable, the Parties will enter into a common interest agreement.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES; COVENANTS

10.1 Licensee Representations, Warranties and Covenants. Licensee represents, warrants and covenants to Licensor as follows, as of the Effective Date:

(a) Due Organization. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated or formed;

(b) Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of Licensee, and constitutes a legal, valid, and binding obligation of Licensee that is enforceable against it in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting or relating to the enforcement of creditors' rights generally, and general principles of equity;

(c) No Conflict. The execution and delivery of this Agreement, the performance of Licensee's obligations hereunder, and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Laws existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation, by-laws or other organizational documents of Licensee; and (iii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of Licensee or any of its Affiliates existing as of the Effective Date;

(d) Other Rights. Neither Licensee nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of Licensee's rights under this Agreement;

(e) No Violation. Neither Licensee nor any of its Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Licensee's obligations hereunder; and

(f) No Debarment. As of the Effective Date, none of Licensee's employees, consultants or contractors:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Laws of any Regulatory Authority;

(ii) has, to Licensee's knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or

pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or has been convicted of a criminal offense that falls within the scope of 42 U.S. C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

(g) Valid Issuance. The Shares have been duly authorized and, when issued, sold and delivered in accordance with this Agreement for the consideration expressed herein will be validly issued, fully paid and nonassessable with no personal liability attaching to the ownership thereof and will be free and clear of all liens, charges and encumbrances of any nature whatsoever except for restrictions on transfer under this Agreement and the Lock Up Agreement, and under applicable federal and state securities laws.

(h) SEC Filings. Licensee has timely made all filings ("SEC Filings") required to be made by it pursuant to applicable securities laws (including without limitation, all filings required under the Securities Exchange Act of 1934), and none of such SEC Filings contains any untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

10.2 Licensor Representations, Warranties and Covenants. Licensor represents, warrants and covenants to Licensee as follows, as of the Effective Date:

(a) Due Organization. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated or formed;

(b) Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of Licensor, and constitutes a legal, valid, and binding obligation of Licensor that is enforceable against it in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting or relating to the enforcement of creditors' rights generally, and general principles of equity;

(c) No Conflict. The execution and delivery of this Agreement, the performance of Licensor's obligations hereunder, and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Laws existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation, by-laws or other organizational documents of Licensor; and (iii) do not and will not conflict with,

violate, breach or constitute a default under any contractual obligations of Licensor or any of its Affiliates existing as of the Effective Date;

(d) Other Rights. Neither Licensor nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of Licensor's rights under this Agreement;

(e) No Violation. Neither Licensor nor any of its Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Licensor's obligations hereunder; and

(f) No Debarment. As of the Effective Date, none of Licensor's employees, consultants or contractors:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Laws of any Regulatory Authority;

(ii) has, to Licensor's knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or has been convicted of a criminal offense that falls within the scope of 42 U.S. C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

(g) Title; Encumbrances. (i) Licensor Controls all Licensor Technology and has sufficient legal or beneficial title, ownership or license, rights, free and clear from any mortgages, pledges, liens, security interests, options, conditional and installment sale agreements, encumbrances, charges or claims of any kind, of or to the Licensor Technology to grant the licenses to Licensee as purported to be granted pursuant to this Agreement; and (ii) Licensor has received no notice that any Third Party has taken any action before any patent and trademark office (or similar Governmental Authority), which would render any of the Licensor Technology invalid or unenforceable;

(h) Notice of Infringement or Misappropriation; Non-Infringement of Rights by Third Parties. To the knowledge of Licensor, no Third Party is infringing or has infringed the Licensor Technology or is misappropriating the Licensor Know-How existing as of the Effective Date. In addition, it has not received any written notice from any Third Party asserting or alleging that (i) any research, Development or manufacture of CX-01 or any Product before the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (ii) the exercise of

Licensee's rights as granted under this Agreement infringes or would infringe any Third Party intellectual property rights;

(i) Non-Infringement of Third Party Rights. To the knowledge of Licensor, the Development, manufacture and Commercialization of CX-01 and any Product can be carried out in the manner reasonably contemplated as of the Effective Date without infringing any issued patents or pending applications Controlled by a Third Party.

(j) Non-Assertion by Third Parties. No Third Party has asserted, or threatened, in writing, legal action asserting, that the Licensor Patents are invalid or unenforceable;

(k) No Proceeding. There are no pending, and to Licensor's knowledge, no threatened, adverse actions, claims, investigations, suits or proceedings against Licensor or any of its Affiliates, at Law or in equity, or before or by any Governmental Authority, involving the Licensor Technology, CX-01 or any Product, nor to Licensor's knowledge has any such adverse action, claim, investigation, suit or proceeding been brought or threatened since the inception of Licensor as a company, in each case, which has been resolved in a manner that impairs any of Licensor's rights in and to any such Licensor Technology, CX-01 or Product;

(l) No Consents. Licensor possesses all permits, licenses, registrations, certificates, authorizations, orders and approvals from the appropriate Governmental Authorities necessary to conduct its business as pertains to CX-01 and any Product and no authorization, consent, approval of a Third Party, nor any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or will be necessary for the (i) valid execution, delivery or performance of this Agreement by Licensor; (ii) the consummation by Licensor of the transactions contemplated hereby; or (iii) prevention of the termination of any right, privilege, license or agreement relating to the Licensor Technology or the continuation thereof following the Effective Date;

(m) No Non-Competition Agreements. Neither Licensor nor any of its Affiliates are bound by any non-competition agreements related to CX-01 or any Product;

(n) Compliance with Laws. To Licensor's knowledge, Licensor has complied with all Laws in connection with the prosecution of the Licensor Patents, including the duty of candor owed to any patent office pursuant to such Laws;

(o) No Grant of Rights. Licensor has not granted any rights with respect to CX-01 or any Product in the Territory, in each case, to any person or entity other than Licensee;

(p) No Unauthorized Use. Neither Licensor nor any of its Affiliates has received any written notice of any unauthorized use, infringement, misappropriation, or dilution by any person, including any current or former employee or consultant of Licensor or its Affiliates, in respect of CX-01 or any Product or any of the Licensor Technology;

(q) Licensor Patents and Patent Applications. (i) The Licensor Patents listed on Schedule 1 are the only patents and patent applications relating to CX-01 and any Product, including

the use and methods of manufacture of CX-01 and any Product, in which Licensor has an interest (whether as owner, licensee or otherwise) either alone or jointly with any Third Party, and (ii) Licensor does not have knowledge of any Information which leads it to believe that any issued patents included in the Licensor Patents are invalid or unenforceable;

(r) Renewal and Maintenance Fees. All material renewal and maintenance fees due as of the Effective Date with respect to the prosecution and maintenance of the Licensor Patents have been paid, and to Licensor's knowledge, all issued patents within the Licensor Patents, and each claim set forth therein are in full force and effect and are valid and enforceable;

(s) Access to Information. Licensor has allowed, and will continue to allow, Licensee access to all material information in Licensor's possession or control (i) containing the results of all Development, preclinical testing and clinical testing of CX-01 and any Product; (ii) concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof with respect to CX-01 and any Product; and (iii) in respect of the Licensor Technology, CX-01 and any Product, all of which information (referred to in clauses (i), (ii) and (iii) above) is true and correct in all material respects;

(t) Inventors. The inventors named in the Licensor Patents are, to Licensor's knowledge, all of the true inventors for such Licensor Patents and each of such inventors has assigned to Licensor or its Affiliates all of his or her right, title and interest to such Licensor Patents and the inventions described therein;

(u) Employee Confidentiality Agreements. All current and former employees and paid consultants (in the case of academic consultants, those acting outside the scope of their academic affiliation) of Licensor and its Affiliates who are or have been substantively involved in the conception, design, review, evaluation, reduction to practice, or development of the Licensor Technology, CX-01 or any Product have executed written contracts or are otherwise obligated to protect the confidential status and value thereof and to vest in Licensor exclusive ownership of the Licensor Technology, CX-01 and any Product;

(v) Third Party Confidentiality. No Third Party has any Licensor Know-How in its possession or control which is not subject to continuing obligations of confidentiality owed to Licensor or its Affiliates for at least the duration of the Term;

(w) Provision of Material Contracts. Licensor has disclosed to Licensee all material contracts relating to the Licensor Technology or the Development, manufacture or Commercialization of CX-01 or any Product and is not in material breach or default of any such material contracts;

(x) Safety and Efficacy. Licensor is not aware of any problems concerning the safety or efficacy of CX-01 or any Product (including any of their ingredients) or of any questions raised by any Regulatory Authority with respect thereto, and Licensor has informed Licensee of all adverse drug reactions known to Licensor relating to CX-01 and each Product or their use;

(y) Good Practices. The Development and manufacture of CX-01 and each Product have been carried out in accordance with GLP, GCP and GMP, as applicable;

(z) Regulatory Matters.

(i) Licensor has provided or made available, when requested by Licensee to conduct its due diligence review, any and all documents and communications in its possession from and to any Governmental Authority, or prepared by any Governmental Authority, related to CX-01 or any Product, that may bear on the compliance with the requirements of any Governmental Authority, including any notice of inspection, inspection report, warning letter, deficiency letter, or similar communication;

(ii) All CX-01 preclinical Development and Clinical Studies conducted by or on behalf of Licensor or any of its Affiliates were, and, if still pending, are being, conducted in in accordance with all applicable Laws, including the FD&C Act and 21 C.F.R. Parts 50, 54, 56, 58 and 312. As applicable to each CX-01 Clinical Study, each Clinical Study was, and if ongoing, is being, conducted pursuant to a valid investigational new drug (IND) application and any other required comparable clinical trial authorizations, and the Licensor has submitted to the FDA (and, as applicable, other comparable Regulatory Authorities) all required reports, including all required safety reports and annual reports;

(iii) Neither Licensor nor any of its Affiliates has received, with respect to CX-01 or any Product, any oral or written communication (including any warning letter, untitled letter, or similar notices) from any Governmental Authority and, there is no action pending or, to Licensor's knowledge, threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that with respect to CX-01 or such Product, Licensor or any of its Affiliates is not currently materially in compliance with any and all Laws implemented by such Governmental Authority. Neither Licensor nor any of its Affiliates has received any written notice from any Governmental Authority or Institutional Review Board (or comparable board or committee) (A) claiming that the research, development, manufacture, use, offer for sale, sale, or import of CX-01 or any Product is not in material compliance with all Laws and permits, or (B) requiring, requesting, or recommending the termination or suspension of any CX-01 Clinical Study;

(iv) To Licensor's knowledge, none of Licensor, any of its Affiliates or any of their respective officers, employees or agents has made, with respect to CX-01 or any Product, an untrue statement of a material fact to any Governmental Authority or failed to disclose a material fact required to be disclosed to such Governmental Authority; and

(v) Licensor has been informed by the FDA that [*].

(aa) Investment Representations.

(i) Licensor is purchasing the Shares for its own account, for investment purposes only and not with a view to resale or distribution;

(ii) Licensor is a corporation with total assets exceeding $5,000,000 and an Accredited Investor as such term is defined under the Securities Act of 1933 (the "1933 Act") and the regulations promulgated thereunder;

(iii) Licensor understands and acknowledges that none of the Shares have been registered under the 1933 Act, or under any state securities or "blue sky" laws of any state of the United States, and, unless so registered, may not be offered or sold in the United States or, directly or indirectly, to U.S. Persons, as that term is defined in Regulation S under the 1933 Act ("Regulation S"), except in accordance with the provisions of Regulation S, pursuant to an effective registration statement under the 1933 Act, or pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the 1933 Act and in each case only in accordance with any applicable state and provincial securities laws;

(iv) immediately following the issuance of the Shares, Licensor (together with its Affiliates and the members of any "group" (within the meaning of Rule 13d-5(b) under the Securities Exchange Act of 1934) in which it or its Affiliates is a member) will not directly or indirectly "beneficially own" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934), or have the right to acquire (including by virtue of beneficially owning securities exercisable for Licensee's common stock) any voting securities of Licensee other than the Shares;

(v) Licensor has (i) reviewed Licensee's filings with the SEC, including its most recently filed annual report on Form 10-K and all subsequent filings, (ii) received all the information that it has requested and that it considers necessary or appropriate for deciding whether to enter into this Agreement and to acquire the Shares, and (iii) has had an opportunity to ask questions and receive answers from Licensee regarding the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares;

(vi) Licensor acknowledges that it is able to fend for itself, can bear the economic risk of its investment and has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the investment in the Shares; it acknowledges that it has not received any legal or tax advice from Licensee or any of its representatives with respect the transactions contemplated hereby and has consulted such legal, tax and investment advisors as it has deemed necessary or appropriate in connection with its purchase of the Shares;

(vii) Licensor is not buying the Shares as a result of any advertisement, article, notice, or other form of general solicitation or general advertising (within the meaning of Regulation D under the 1933 Act) regarding the Shares;

(viii) Licensor is not engaged in the business of a broker-dealer, is not a registered broker dealer under the Securities Exchange Act of 1934, and is not a member of the Financial Industry Regulatory Authority, Inc.;

(ix) Licensor's principal executive office, place of business and the location where it determined to acquire the Shares is in Florida;

(x) Licensor has not, directly or indirectly, nor has any person acting on behalf of or pursuant to any understanding with it, at any time since the 30th day immediately prior to the date of this Agreement, engaged in any transactions in the securities of Licensee (including any short sales as defined in Rule 200 promulgated under Regulation SHO under the Securities Exchange Act of 1934 and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, swaps and similar arrangements) or made any bids with any broker or dealer to purchase Licensee's common stock; and

(xi) no person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon Licensee for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of Licensor.

(bb) Assets and Revenues. As of the date of its most recent regularly prepared financial statements, Licensor had total assets of less than $18 million and annual revenues of less than $18 million.

10.3 Covenants.

(a) No Debarment. In the course of the Development and Commercialization of CX-01 and any Product, neither Party will use any employee, consultant or contractor:

(i) who has been debarred under Section 306(a) or 306(b) of the FD&C Act or pursuant to the analogous Laws of any Regulatory Authority;

(ii) who, to such Party's knowledge, has been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or otherwise pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority, during the employee's or consultant's employment or contract term with such Party; and

(iii) who is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or who has been convicted of a criminal offense that falls within the scope of 42 U.S. C. §1320a-7 but has not yet been excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

(b) Each Party will notify the other Party promptly, but in no event later than five (5) Business Days, upon becoming aware that any of its employees or consultants has been excluded, debarred, suspended or is otherwise ineligible, or is the subject of exclusion, debarment or suspension proceedings by any Regulatory Authority.

(c) Compliance. Each Party and its Affiliates will comply in all material respects with all Laws in the Development, manufacture and Commercialization of CX-01 and any Products and the performance of its obligations under this Agreement, including where applicable the statutes,

regulations and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S. C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other healthcare programs, as defined in 42 U.S. C. § 1320a-7b(f), the Foreign Corrupt Practices Act of 1977, and the UK Bribery Act of 2010, each as may be amended from time to time and each to the extent applicable;

(d) Inventors. Licensor shall reimburse the inventors named in the Licensor Patents and Licensee shall have no obligation in respect of such reimbursement;

(e) No Violation. Neither Licensor nor any of its Affiliates will enter into or otherwise have any obligation to any person or entity, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Licensor's obligations hereunder;

(f) Third Party Confidentiality. Licensor will maintain the confidentiality of the Licensor Know-How, and will ensure that no Third Party has any Licensor Know-How in its possession or Control which is not subject to continuing obligations of confidentiality owed to Licensor or its Affiliates for at least the duration of the Term; and

(g) The CREATE Act. Each Party acknowledges and agrees that:

(i) the provisions herein are intended to encompass and include a joint research agreement for the performance of experimental, developmental and research work as contemplated by 35 U.S.C. § 102(c), and that any invention made in connection with the activities contemplated in this Agreement, whether made solely by or on behalf of one Party or jointly by or on behalf of both Parties, is intended to and should have the benefit of the rights and protections conferred by Public Law 108-453, the Cooperative Research and Enhancement Act of 2004 as codified in 35 U.S.C. § 102(c) (the "CREATE Act");

(ii) in the event that a Party seeks to rely on the foregoing and invoke the CREATE Act with respect to any invention that is the subject of a patent application filed by or on behalf of such Party, such Party will give prior written notice(s) to the other Party of its intent to invoke the CREATE Act and of each submission or disclosure such Party intends to make to any patent and trademark office (or similar Governmental Authority) pursuant to the CREATE Act, including: (A) any disclosure of or regarding the existence or contents of this Agreement to any patent and trademark office (or similar Governmental Authority); (B) the disclosure of any "subject matter developed by the other Party" (as such term is used in the CREATE Act) in, without limitation, an information disclosure statement, or (C) the filing of any terminal disclaimer over the intellectual property of the other Party, it being agreed that no such submission, disclosure or filing shall be made by such Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed;

(iii) without limiting Section 10.3(g)(ii) above, it shall not be a violation of confidentiality obligations hereunder for a Party, as necessary in connection with the invocation of the CREATE Act, to disclose to any patent and trademark office (or similar Governmental

Authority) (A) the intellectual property of the other Party in, without limitation, an information disclosure statement or (B) this Agreement, provided that such Party exercises reasonable efforts to limit the scope of such disclosure as strictly necessary to invoke the CREATE Act, including by reasonably redacting the material terms of this Agreement before any such disclosure; and

(iv) without limiting Section 10.3(g)(ii) above, each Party will provide reasonable cooperation to the other Party in connection with such other Party's efforts to invoke and rely on the CREATE Act.

(h) MTAs. Licensor hereby covenants to use its Commercially Reasonable Efforts to assign, grant, convey and transfer to Licensee all of the rights, title and interests of Licensor in and to each of the MTAs, as soon as practicable after the Effective Date. Until such time as the assignment of each of the MTAs is effective, Licensor may only take any action under each such MTA at Licensee's direction and upon Licensee's prior written consent.

10.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification by Licensor. Licensor will, at its sole expense, defend, indemnify, and hold Licensee and its Affiliates and their respective officers, directors, shareholders or owners, employees, and agents (the "Licensee Indemnitees") harmless from and against any and all Third Party claims, suits, proceedings, damages, losses, liabilities, taxes, costs, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries (collectively, "Claims") to the extent that such Claims arise out of, are based on, or result from (a) Development of CX-01 or any Product by or on behalf of Licensor or its Affiliates or its or their sublicensees (other than Licensee and its Affiliates), (b) the breach of any of Licensor's obligations under this Agreement, including Licensor's representations and warranties, covenants and agreements, or (c) the willful misconduct or negligent acts of Licensor, its Affiliates, or the officers, directors, employees, or agents of Licensor or its Affiliates. The foregoing indemnity obligation will not apply (i) to the extent that (x) the Licensee Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Licensor's defense of the relevant Claims is prejudiced by such failure or (y) such Claims arise out of or result from the gross negligence or willful misconduct of Licensee or its Affiliates, or any related breach by Licensee of its representations, warranties or covenants or any other obligation of Licensee hereunder; or (ii) to Claims for which Licensee has an obligation to indemnify Licensor pursuant to Section 11.2, as to which Claims each Party will indemnify the other to the extent of its respective liability for such Claims.

11.2 Indemnification by Licensee. Licensee will, at its sole expense, defend, indemnify, and hold Licensor and its Affiliates and their respective officers, directors, shareholders or owners, employees, and agents (the "Licensor Indemnitees") harmless from and against any and all Third Party claims to the extent that such Claims arise out of, are based on, or result from (a) Development or Commercialization of CX-01 or any Products by or on behalf of Licensee or its Affiliates or its or their Sublicensees, (b) the breach of any of Licensee's obligations under this Agreement, including Licensee's representations and warranties, covenants and agreements or (c) the willful misconduct or negligent acts of Licensee, its Affiliates, or the officers, directors, employees, or agents of Licensee or its Affiliates. The foregoing indemnity obligation will not apply (i) to the extent that (x) the Licensor Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Licensee's defense of the relevant Claims is prejudiced by such failure or (y) such Claims arise out of or result from the gross negligence or willful misconduct of Licensor or its Affiliates, or any related breach by Licensor of its representations, warranties or covenants hereunder; or (ii) to Claims for which Licensor has an obligation to indemnify Licensee pursuant to Section 11.1, as to which Claims each Party will indemnify the other to the extent of its respective liability for such Claims.

11.3 Indemnification Procedures. The Party claiming indemnity under this ARTICLE 11 (the "Indemnified Party") will give written notice to the Party from whom indemnity is being sought (the "Indemnifying Party") promptly after learning of a Claim. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party may assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party will not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this ARTICLE 11.

11.4 Limitation of Liability. EXCEPT (A) IN THE EVENT OF THE FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 12, (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 11 OR (C) IN CONNECTION WITH ANY MISREPRESENTATION, BREACH OR INACCURACY OF ANY REPRESENTATION MADE BY A PARTY, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR SUBLICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, REMOTE, EXEMPLARY OR SPECULATIVE DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS, ARISING

FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES OR THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY.

11.5 Insurance. Each Party shall procure and maintain product liability insurance in the amount of [*], or shall self-insure, in each case in a manner adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested or commercially distributed or sold by such Party. Each Party shall procure insurance or self-insure at its own expense. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with written notice of cancellation or non-renewal of such insurance.

ARTICLE 12

CONFIDENTIALITY

12.1 Confidentiality. Each Party agrees that, during the Term and, subject to Section 12.5, for a period of ten (10) years thereafter, it and its Affiliates will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it or its Affiliate by or on behalf of the other Party or its Affiliate pursuant to this Agreement, except to the extent expressly authorized by this Agreement or as otherwise agreed to in writing by the Parties. The foregoing confidentiality and non-use obligations do not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party or its Affiliate;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party or its Affiliate;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliate in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party or its Affiliate; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

12.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 12.1, a Party or its Affiliate may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent rights as contemplated by this Agreement; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of Product; or (iii) for prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, attorneys, accountants, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; *provided* that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; *provided* that in each case, the disclosees are bound by written obligations of confidentiality and non-use having a minimum term of five (5) years from the date of the relevant agreement or the date of disclosure, as set forth in such agreement; or

(d) such disclosure is reasonably necessary to comply with Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or other order.

Notwithstanding the foregoing, if a Party or its Affiliate is required to make a disclosure of the other Party's Confidential Information pursuant to Section 12.2(a) or 12.2(d), such Party will promptly notify the other Party of such required disclosure and, upon the other Party's request, such Party and its Affiliates will use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

12.3 Technical Publication. The Parties will ensure that all publications, and other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement or otherwise relating to any Product (each of the foregoing, a "Publication") comply with the strategy established by the JDC. Neither Party nor their Affiliates will submit for publication, publish or present a Publication without the opportunity for prior review by the non-publishing Party, except to the extent required by Laws. A Party seeking, or whose Affiliate is seeking, to submit, publish or present a Publication will provide the non-publishing Party the opportunity to review and comment on the proposed Publication at least fifteen (15) days before its intended submission for publication or presentation. The non-publishing Party will provide the Party seeking, or whose Affiliate is seeking, to publish or present with its comments in writing, if any, within ten (10) days after receipt of such proposed Publication. The Party seeking, or whose Affiliate is seeking, to publish or present will consider in good faith any comments thereto provided by the non-publishing Party and will comply with the non-publishing Party's request to remove any and all of the non-publishing Party's Confidential Information from the proposed Publication. In addition,

the Party seeking, or whose Affiliate is seeking, to publish or present will delay the submission for a period of up to thirty (30) days if the non-publishing Party can demonstrate reasonable need for such delay to prepare and file a patent application for which it has prosecution control pursuant to this Agreement. If the non-publishing Party fails to provide its comments to the Party seeking, or whose Affiliate is seeking, to publish or present within such ten (10)-day period, the non-publishing Party will be deemed not to have any comments, and the Party seeking, or whose Affiliate is seeking, to publish or present may submit for publication or present in accordance with this Section 12.3 after the fifteen (15)-day period has elapsed. The Party seeking, or whose Affiliate is seeking, to publish or present will provide the non-publishing Party a copy of the manuscript, abstract or presentation at the time of the submission or presentation, as applicable. Each Party agrees to acknowledge the contributions of the non-publishing Party and its Affiliates and their employees in all publications, as scientifically appropriate.

12.4 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 12.4.

(b) The Parties will make a joint public announcement of the execution of this Agreement in a mutually agreed form, which will be issued within four (4) Business Days after the Effective Date, as agreed by the Parties. In addition, Licensee will file a Current Report on Form 8-K with the SEC.

(c) After release of such press release and filing of Licensee's Current Report on Form 8-K, if either Party or its Affiliate desires to make a public announcement concerning the material terms of this Agreement, or any clinical or regulatory announcements, such Party will give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided), such approval not to be unreasonably withheld. A Party commenting on such a proposed announcement will provide its comments, if any, within three (3) Business Days after receiving the announcement for review, or such shorter period as may be reasonably required in order for the proposing Party to comply with any applicable deadline for making such announcement (as such deadline is communicated by the proposing Party to the commenting Party). In addition, where required by Laws, including regulations promulgated by applicable securities exchanges, such Party or its Affiliate may make a press release (or SEC or other regulatory filing) announcing the achievement of each milestone under this Agreement as it is achieved, the achievements of Regulatory Approvals in the Territory as they occur, or any other material event with respect to this Agreement or the Parties' performance thereof, subject only to the review procedure set forth in the preceding sentence; *provided* that the review period will be reduced to two (2) Business Days (or such shorter period as may be reasonably required in order for the proposing Party to comply with any applicable deadline for making such press release (or SEC or other regulatory filing), as such deadline is communicated by the proposing Party to the commenting Party) if the deadline for making such disclosure is five (5) or fewer Business Days after such achievement or event. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release (or SEC

or other regulatory filing) within the prescribed time for commentary, but will not withhold, condition, or delay its consent to disclosure of the information that the relevant milestone or Regulatory Approval has been achieved or material event has occurred. Neither Party nor their Affiliates are required to seek the permission of the other Party to repeat or summarize any information regarding the terms of this Agreement that has already been substantially publicly disclosed by such Party or its Affiliate, or by the other Party or its Affiliate, in accordance with this Section 12.4, if such information remains accurate as of such time. Notwithstanding the foregoing, Licensee shall not be obligated to obtain Licensor's approval of, or to provide Licensor the opportunity to review and comment on, Licensee's public announcements concerning the Product, provided that Licensee provides Licensor with reasonable prior notice of material public announcements with respect thereto.

(d) The Parties acknowledge that either or both Parties may be obligated to file under Laws a copy of this Agreement with the U.S. Securities and Exchange Commission ("SEC") or other Governmental Authorities. Each Party will make such a required filing and will request confidential treatment of the commercial terms and sensitive technical or other competitively sensitive terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show the provisions for which such Party intends to seek confidential treatment and will reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

12.5 Return of Confidential Information. Except as otherwise set forth in this Agreement, upon termination of this Agreement, the receiving Party will promptly return all of the disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the receiving Party may retain a reasonable number of archival copies as may be required by law or its standard document retention policies.

12.6 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it will promptly notify the other Party of such unauthorized use or disclosure.

12.7 Exclusive Property. All Confidential Information is the sole and exclusive property of the disclosing Party and the permitted use thereof by the receiving Party for purposes of its performance hereunder will not be deemed a license or other right of the receiving Party to use any such Confidential Information for any other purpose.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement becomes effective on the Effective Date, and, unless sooner terminated as specifically provided in this Agreement, continues in effect on a country-by-country basis until the expiration of all payment obligations hereunder (the "Term").

13.2 Unilateral Termination by Licensee.

(a) Termination Upon Written Notice. Notwithstanding any other provision of this Agreement, Licensee may at any time terminate this Agreement, on a country-by-country basis, or in its entirety, upon sixty (60) days' prior written notice to Licensor.

(b) Effect of Termination. Upon termination of this Agreement pursuant to Section 13.2(a), (i) all rights and the licenses granted to Licensee by Licensor for any terminated country(ies) shall immediately terminate and, subject to this Section 13.2(b), all future obligations of each Party and its Affiliates under this Agreement with respect to any terminated country(ies) will immediately cease, (ii) Licensee will stop recruiting for any ongoing Clinical Studies for the terminated country(ies) and will terminate them in accordance with ethical guidelines, and (iii) at Licensor's request, Licensee shall negotiate in good faith with Licensor commercially reasonable financial terms upon which Licensee would assign to Licensor rights in any Information, Inventions and Regulatory Materials controlled by Licensee with respect to Product(s) relating to the terminated portions of this Agreement.

13.3 Termination for Breach.

(a) Termination Upon Written Notice. Each Party (the "Non-Breaching Party") may terminate this Agreement on a country-by-country basis, or in its entirety, immediately upon written notice to the other Party (the "Breaching Party") if the Breaching Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail (a "Default Notice"), fails to cure such material breach within ninety (90) days after delivery of the Default Notice (or within thirty (30) days after delivery of the Default Notice if such material breach is solely based on the Breaching Party's failure to pay any amounts due hereunder). If a Party gives notice to the Breaching Party pursuant this Section 13.3(a) as a result of a material breach (or alleged material breach) by the Breaching Party and, on or before the end of the cure period therefor, either Party has referred the matter to arbitration pursuant to Section 14.1, in either case where the Breaching Party is in good faith disputing such basis for termination pursuant to this Section 13.3(a), then (i) such cure period will be suspended and (ii) this Agreement will not terminate, unless and until the chief executive officer of Licensor and the chief executive officer of Licensee resolve the dispute or the arbitrators issue a final ruling or award upholding such basis for termination (or unless and until the Breaching Party is no longer disputing such basis in good faith, if earlier). If the arbitrators issue a final ruling or award upholding such basis for termination, then the cure period will resume, and the Breaching Party will have the remainder of the cure period to cure the material breach. If the material breach is so cured within the remainder of the cure period, then this Agreement will remain in full force and effect, otherwise this Agreement will terminate. If the arbitrators issue a final ruling rejecting such basis for termination, then this Agreement will remain in full force and effect.

(b) Effect of Termination by Licensee. Upon termination by Licensee pursuant to Section 13.3(a), (i) all rights and the licenses granted to Licensee by Licensor under the terminated portions of this Agreement shall immediately terminate and, subject to this Section 13.3(b), all future obligations of each Party and its Affiliates under the terminated portions of this Agreement will immediately cease, (ii) Licensee will stop recruiting for any ongoing Clinical Studies with

respect to the terminated portions of this Agreement and will terminate them in accordance with ethical guidelines, and (iii) at Licensor's request, Licensee shall negotiate in good faith with Licensor commercially reasonable financial terms upon which Licensee would assign to Licensor rights in any Information, Inventions and Regulatory Materials controlled by Licensee with respect to Product(s) relating to the terminated portions of this Agreement.

(c) Effect of Termination by Licensor. Upon termination by Licensor pursuant to Section 13.3(a), (i) all rights and the licenses granted to Licensee by Licensor for any terminated country(ies) shall immediately terminate and, subject to this Section 13.3(c), all future obligations of each Party and its Affiliates under this Agreement with respect to any terminated country(ies) will immediately cease, (ii) Licensee will stop recruiting for any ongoing Clinical Studies for any terminated country(ies) and will terminate them in accordance with ethical guidelines, and (iii) all rights in any Product(s), Licensor Technology and Licensee Technology (other than Licensee Technology that is purchased from a Third Party other than Licensor) and Regulatory Materials with respect to such terminated country(ies), shall be automatically assigned to Licensor.

13.4 Survival. Termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued before the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions will survive any expiration or termination of this Agreement: ARTICLE 1 (Definitions), Section 2.4 (Exclusivity Covenant), Section 8.7 (Records), Section 8.8 (Audits), Section 8.9 (Taxes), ARTICLE 11 (Indemnification), ARTICLE 12 (Confidentiality), ARTICLE 13 (Term and Termination), ARTICLE 14 (Dispute Resolution), and ARTICLE 15 (Miscellaneous).

ARTICLE 14

DISPUTE RESOLUTION

14.1 Arbitration. In the event of any disputes, controversies or differences between the Parties (except for disputes arising from the JDC, which will be handled pursuant to Section 3.1(d)), arising out of, in relation to, or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the validity, construction, interpretation, enforceability, breach, performance, application, or termination of this Agreement a ("Dispute"), then upon the written request of either Party, the Parties agree to meet and discuss in good faith an amicable resolution thereof, which good faith efforts include at least one in-person meeting between the most senior executive officer of Licensor and the chief executive officer of Licensee (or their respective designees). If the Dispute is not resolved within thirty (30) days following the written request for amicable resolution, then either Party may then initiate arbitration under this Section 14.1. Any Dispute that the Parties do not resolve through amicable resolution will be settled by final and binding arbitration administered by JAMS, Inc., the alternative dispute resolution company formerly known as Judicial Arbitration and Mediation Services, Inc., pursuant to its Comprehensive Arbitration Rules and Procedures then in effect (the "JAMS Rules"), except as otherwise provided. The number of the arbitrators will be three, with each Party selecting one arbitrator and those two arbitrators selected by the Parties then selecting the third arbitrator. The arbitration will be conducted in New York, New York. The language of the arbitration will be English. Judgment on the award may be entered in any court having jurisdiction. Except as may be required

by Law, neither Party may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

14.2 Equitable Relief. Notwithstanding Section 14.1, each Party acknowledges that its breach of ARTICLE 12 may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated by damages in an action at law. By reason thereof, each Party agrees that the other Party may, in addition to any other remedies it may have under this Agreement or otherwise, seek preliminary and permanent injunctive and other equitable relief from any state or federal court of competent jurisdiction in New York, New York to prevent or curtail any actual or threatened breach of ARTICLE 12 that is reasonably likely to cause it irreparable harm. In addition, notwithstanding Section 14.1, to the fullest extent provided by Law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect a Party's rights or enforce a Party's obligations under this Agreement pending final resolution of any claims related thereto pursuant to the dispute resolution procedure set forth in Section 14.1.

14.3 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof are governed by and construed under the Laws of the State of New York, without giving effect to any choice of law principles that would require the application of the Laws of a different state.

14.4 Patent and Trademark Disputes. Notwithstanding Section 14.1, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent or trademark rights outside the U.S. covering the manufacture, use, importation, offer for sale or sale of Product will be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

ARTICLE 15

MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, together with the Development Plan, and any other documents delivered pursuant hereto or thereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and thereto and their Affiliates with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter of this Agreement other than as are set forth in this Agreement and the Development Plan. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse will continue for so long as the condition constituting force majeure continues and the non-

performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure includes conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, and storm or like catastrophe. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than sixty (60) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement to mitigate the delays caused by such force majeure.

15.3 Notices. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by email with non-automated confirmed read receipt or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Licensor:

Cantex Pharmaceuticals, Inc.
1792 Bell Tower Lane
Weston, FL 33326
Attn: Chief Executive Officer
Email: [*]

With copies to (which will not constitute notice):

The Law Office of Rodney H. Bell, P.A.
4200 Santa Maria Street
Coral Gables, FL 33146
Attn: Rodney H. Bell
Email: [*]

If to Licensee:

Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713
Attn: Chief Executive Officer
Email: [*]

With a copy to (which will not constitute notice):

Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713
Attn: General Counsel
Email: [*]

15.4 No Strict Construction; Interpretation; Headings. The language in this Agreement is to be construed in all cases according to its fair meaning. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender applies to all genders. The word "or" is used in the disjunctive sense and the word "and" is used in the conjunctive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes", whether or not followed by "without limitation" or "including, but not limited to," or words of similar import, shall be construed to mean in each case including, without limiting the generality of any description preceding such term. The Parties agree that no meaning should be inferred about the use of "without limitation" or "including, but not limited to" in some instances but not others. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws will be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference to any person will be construed to include the person's successors and permitted assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (v) any reference to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, (vi) all references to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits and Schedules to this Agreement, (vii) the word "days" means calendar days unless otherwise specified, and (viii) the words "copy" and "copies" and words of similar import when used in this Agreement include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

15.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to its Affiliates or to a Third Party successor or transferee to all or substantially all of the assets of such Party in the Field to which this Agreement relates (such Third Party, an "Acquiror"), whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations; *provided* that in the case of an assignment to an Affiliate, the assigning Party shall remain primarily liable for performance under this Agreement. Any permitted assignment will be binding on the

successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 is null, void and of no legal effect.

15.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement is a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.7 Further Assurances and Actions. Each Party, upon the request of the other Party, whether before or after the Effective Date and without further consideration, will do, execute, acknowledge, and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary to consummate or implement expeditiously the transactions contemplated by this Agreement.

15.8 Severability. Each of the provisions contained in this Agreement will be severable, and the unenforceability of one will not affect the enforceability of any others or of the remainder of this Agreement. If any one or more of the provisions of this Agreement, or the application thereof in any circumstances, is held to be invalid, illegal, or unenforceable in any respect for any reason, the Parties will negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided*, *however*, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions of this Agreement will not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto will be enforceable to the fullest extent permitted by Law.

15.9 No Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver, delay or the failure of any Party to enforce or exercise any term, condition or part of this Agreement at any time or in any one or more instances will not be deemed to be or construed as a waiver of the same or any other term, condition or part, nor will it forfeit any rights, power or privilege to future enforcement thereof. No single or partial exercise of any right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Law, (a) no claim or right arising out of this Agreement or any of the documents referred to in this Agreement can be discharged by one Party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other Party; (b) no waiver that may be given by a Party will be applicable except in

the specific instance for which it is given; and (c) no notice to or demand on one Party will be deemed to be a waiver of any obligation of that Party or of the right of the Party giving such notice or demand to take further action without notice or demand as provided in this Agreement or the documents referred to in this Agreement. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

15.10 Relationship of the Parties. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Licensor's legal relationship to Licensee under this Agreement will be that of independent contractor and nothing in this Agreement gives either Party the power or authority to act for, bind, or commit the other Party in any way. This Agreement is not a partnership agreement. Nothing in this Agreement will be construed to establish a relationship of partners, principal and agent or joint venturers between the Parties or their respective employees or Affiliates. Nothing contained in this Agreement shall be construed to create a "separate entity" or "business entity" within the meaning of the U.S. Internal Revenue Code or the regulations thereunder and any foreign equivalents thereto. Neither Licensee nor Licensor will make any statements, representations, or commitments of any kind, or to take any action that is binding on the other, without the prior consent of the other Party to do so.

15.11 English Language. This Agreement was prepared in the English language, which language governs the interpretation of, and any dispute regarding, the terms of this Agreement.

15.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which is an original, but all of which together constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or by PDF. In addition, facsimile or PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a facsimile or PDF signature by any Party will constitute due execution and delivery of this Agreement.

15.13 Schedules. The disclosure of any matter in any Section of or on any Schedule to this Agreement will only be deemed to be a disclosure for the Section or subsection of this Agreement to which it corresponds in number, unless the applicability of such Schedule to any other Section is readily apparent. The disclosure of any matter in any Schedule to this Agreement will expressly not be deemed to (a) constitute an admission by either Party hereto, or (b) imply that any such matter is material for purposes of this Agreement.

15.14 Expenses. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

15.15 Section 365(n). The Parties acknowledge and agree that the licenses granted by the Parties pursuant to Sections 2.1 and 2.2 and all other rights granted under or pursuant to this Agreement are, for purposes of Section 365(n), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code (or analogous foreign provisions), and that this Agreement is an executory contract governed by Section 365(n) if a bankruptcy proceeding is commenced involving either Party (as licensor hereunder). Licensee, as the licensee of such rights under Section 2.1, retains and may fully exercise all of its rights and elections under the Bankruptcy Code. The foregoing provisions of this Section 15.15 are without prejudice to any rights the Parties may have arising under the Bankruptcy Code or other Laws.

[*Remainder of this page intentionally left blank***]**

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

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

CANTEX PHARMACEUTICALS, INC.	**CHIMERIX, INC.**
By: /s/ Stephen Marcus	By: /s/ Mike Sherman
Name: Stephen Marcus	Name: Mike Sherman
Title: CEO	Title: President and CEO

SIGNATURE PAGE TO LICENSE AND DEVELOPMENT AGREEMENT

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

EXHIBIT A

[*]

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

SCHEDULE 1

LICENSOR PATENTS

[*]

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

SUPPLY AGREEMENT

This SUPPLY AGREEMENT (this "**Agreement**") is made and entered into as of October 5, 2015 ("**Effective Date**"), by and between CANTEX Pharmaceuticals, Inc. formerly known as PARINGENIX, INC., a Delaware corporation ("**Cantex**") and SCIENTIFIC PROTEIN LABORATORIES LLC, a Delaware limited liability company ("**SPL**").

RECITALS

WHEREAS, Cantex is the inventor and owner of certain proprietary technology relating to "ODSH" (as defined herein) which Cantex is using in the development of innovative therapeutic products to enhance the anticancer effects of existing chemotherapy and radiation therapy while reducing the toxicity of those therapies.

WHEREAS, the Parties entered into a certain Supply Agreement for the production of ODSH dated August 3, 2011 ("**Prior Agreement**") pursuant to which SPL agreed to manufacture and supply to Cantex an agreed quantity of ODSH in accordance with the terms of the Prior Agreement.

WHEREAS, the Parties desire to terminate the Prior Agreement and enter into this Agreement pursuant to which SPL shall procure, qualify, manufacture and sell API (as defined below) to Cantex for the production of Products in accordance with the terms hereof, but the Parties acknowledge that SPL created Intellectual Property for and on behalf of Cantex under the Prior Agreement which is included in Cantex Intellectual Property in accordance with the terms of such Prior Agreement and as described in Article VII of this Agreement.

NOW, **THEREFORE**, in consideration of the mutual promises and covenants herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties hereto agree as follows:

ARTICLE I

DEFINITIONS

Capitalized words and phrases used in this Agreement shall have the following meanings:

1.1 **"Act"** means the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

1.2 **"Affiliate"** means, with reference to a specified Person, a Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, the specified Person. For purposes of this paragraph, "control" shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least 50% of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least

50% of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.3 **"API"** (also referred to interchangeably in this agreement as "**O-Desulfated Heparin**" and/or "**ODSH**") shall mean both [*], the active pharmaceutical ingredient for the Product. The API will start from Heparin and shall conform to the API Specifications.

1.1 **"API Purchase Price"** shall have the meaning set forth in Section 2.2.

1.2 "**API Specifications**" means the specifications set forth on Exhibit A attached hereto.

1.3 **"Arbitrator"** shall mean, as the case may be, the independent accounting firm described in Section 2.4, the expert described in Section 2.3 (Facility Expansion) or the person described in Section 12.3(b).

1.4 **"cGMPs"** means current good manufacturing practice and standards as provided for (and as amended from time to time) in the European Community Directive 91/356/EEC (principles and guidelines of good manufacturing practice for medicinal Products) and in the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 C.F.R. §§ 210 and 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by the ICH Harmonized Tripartite Guideline, Good Manufacturing Practice, Guide for Active Pharmaceutical Ingredients, Q7a and subject to any arrangements, additions or clarifications, and respective roles and responsibilities, agreed from time to time between the Parties as set forth in the Quality Agreement.

1.5 **"Cantex Intellectual Property**" means collectively all Cantex Intellectual Property Rights in existence on the date hereof and as described in Article VII of this Agreement.

1.6 **"Certificate of Analysis"** has the meaning set forth in Section 2.7(a).

1.7 **"Change of Control"** shall mean (a) a merger, consolidation, stock sale or similar transaction with respect to a Party in which the stockholder or limited liability company members of such Party immediately prior to such transaction would own, in the aggregate, less than 50% of the total combined voting power of all classes of stock or membership interests of the Party normally entitled to vote for the election of directors, managers or other governing body of the Party, or (b) the sale by such Party of all or substantially all of the assets of such Party in one transaction or in a series of related transactions; or (c) other transactions the intent of which is to sell all or substantially all of the assets or business of such Party.

1.8 **"Claim"** has the meaning set forth in Section 10.3.

1.9 **"Commercially Reasonable Efforts"** shall mean, with respect to each Party, efforts and commitment of resources in accordance with such Party's reasonable business, legal, medical, and scientific judgment that are consistent with the efforts and resources that such Party uses for other products owned by it or to which it has exclusive rights, that are of similar market

potential and at a similar stage in their life cycle, taking into account the competitiveness of the marketplace, the regulatory structure involved, the profitability of the applicable products and other relevant factors, including technical, legal, scientific, medical, sales performance, and/or marketing factors, including the good faith performance of any associated commitments under this Agreement.

1.10 **"Competitive Product"** has the meaning set forth in Section 2.10 below.

1.11 **"Confidentiality Agreement"** has the meaning set forth in Section 8.2.

1.12 **"Confidential Information"** shall mean "Confidential Information" as defined in the Confidentiality Agreement.

1.13 **"Conforming API"** has the meaning set forth in Section 4.6.

1.14 **"Dispute"** has the meaning set forth in Section 12.3(a).

1.15 **"Dispute Notice"** has the meaning set forth in Section 12.3(a).

1.16 **"Ex-Works"** means "Ex-works" as that term is defined in INCOTERMS 2010.

1.17 **"Facility Expansion"** shall have the meaning set forth in Section 2.3.

1.18 **"Facility Ready Date"** has the meaning set forth in Section 2.2.

1.19 **"FDA"** means the U.S. Food and Drug Administration, or any successor entity thereto.

1.20 **"Event of Force Majeure"** has the meaning set forth in Section 12.1.

1.21 "**Governmental Authority"** means any federal, state, local, municipal, foreign or other governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official or entity and any court or other tribunal, including an arbitral tribunal), any multi-national organization or body, or any similar body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing power of any nature.

1.22 **"Heparin"** means the active pharmaceutical ingredient Heparin Sodium, USP produced by SPL and produced only from raw materials sourced and originating within North America.

1.23 **"Indemnitee"** has the meaning set forth in Section 10.3.

1.24 **"Indemnitor"** has the meaning set forth in Section 10.3.

1.25 "**Intellectual Property Rights"** means all intellectual property rights including without limitation, all patents, patent applications, supplementary protection certificates, petty

patents, utility models, trademarks, database rights, rights in designs, copyrights and topography rights (whether or not any of these rights are registered, and including applications and the right to apply for registration of any such rights), formulas, formulations, specifications, production methods, analytical methods and all inventions, know-how, trade secrets, techniques and confidential information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term, and together with any improvements thereto or derivatives therefrom and all renewals or extensions.

1.26 **"Judgment"** means any award, decision, injunction, judgment, order, ruling, subpoena, or verdict of any court, arbitral tribunal, administrative agency or other Governmental Authority having jurisdiction over a Party.

1.27 **"Law"** means any applicable federal, state, local, municipal, foreign, international, multinational or other administrative order, constitution, law, ordinance, principle of common law, regulation, statute or treaty.

1.28 "**Not Pursuing**" has the meaning set forth in Section 11.2(a)(iii)

1.29 **"Parties"** or **"Party"** means Cantex and/or SPL collectively or individually as the case may be.

1.30 **"Permit"** has the meaning set forth in Section 6.1.

1.31 **"Person"** means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, Governmental Authority or other entity.

1.32 **"Preliminary Period"** has the meaning set forth in Section 2.2.

1.33 **"Price Negotiation Period"** has the meaning set forth in Section 2.4.

1.34 **"Product"** shall mean any proprietary drug candidate which has been or may be developed for any specified human or veterinary indication by Cantex which uses any form of [*] active pharmaceutical ingredient.

1.35 **"Quality Agreement**" has the meaning set forth in Section 4.1.

1.36 **"Raw Material Costs"** means the actual out of pocket costs incurred by SPL in acquiring and transporting the raw materials necessary to produce to the API.

1.37 **"Regulatory Approval"** means the approvals or authorizations of the FDA or any other regulatory authorities necessary for the marketing and sale of a Product in the Territory.

1.38 **"Regulatory Authority"** means the FDA, or any Governmental Authority that performs a function for a political subdivision similar to the function performed by the FDA for the United States with regard to the approval, licensing, registration or authorization to test,

manufacture, promote, market, distribute, use, store, import, transport or sell Products in a defined territory or political subdivision(s).

1.39 **"Regulatory Requirements"** means (a) any and all permits, licenses, filings and certifications required by the FDA or other Regulatory Authorities, and compliance with the cGMPs of the FDA or other Regulatory Authorities, applicable to any manufacturing or processing activities under this Agreement and (b) any Laws, rules, guidelines, regulations, and standards of any Governmental Authority, whether within or outside the United States (including the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Drug Enforcement Administration (DEA) and state and local authorities), that apply to any manufacturing or processing activities under this Agreement.

1.40 "**Representative**" means, with respect to a particular Person, any director, manager, officer, employee, agent, consultant, legal counsel, accountants and financial advisors.

1.41 **"SEC"** means United States Securities and Exchange Commission.

1.42 "**SPL Intellectual Property**" means collectively all SPL Intellectual Property Rights in existence on the date hereof and as described in Article VII of this Agreement.

1.43 "**SPL's Waunakee Facility**" means SPL's Waunakee Facility located at 700 E. Main Street Waunakee, WI 53597.

1.44 **"Term"** has the meaning set forth in Section 11.1.

1.45 **"Territory"** means the world.

1.46 **"Third Party"** means any Person other than the Parties and their respective Representatives and Affiliates.

1.47 **"Transfer Taxes"** has the meaning set forth in Section 3.2.

1.48 **"Two-Year Period"** has the meaning set forth in Section 2.4.

ARTICLE II

SUPPLY, PURCHASE ORDER AND DELIVERY

2.1 Supply of Products. During the Term and subject to the terms and conditions hereof, SPL shall manufacture and sell the API to Cantex, and Cantex shall purchase the API produced by SPL at a rate estimated to be [*] per year at SPL's current small scale facility for manufacturing API. Following the Facility Expansion, the amount of API to be purchased shall be determined in good faith by the Parties. Except as expressly provided herein, SPL shall be the exclusive supplier of the API. All such API shall be sold to Cantex free and clear of all liens and security interests.

2.2 Purchase Price for the Preliminary Period. The purchase price for the API (the "**API Purchase Price**") during the [*] of the Preliminary Period of the Term (as defined in Article

11 below) of this Agreement will be U.S. [*], Ex-Works at SPL's Waunakee facility. The "**Preliminary Period**" shall mean the period commencing on the date hereof and ending on the date the Facility Expansion receives all necessary regulatory approvals with respect to the supply of the API and is ready for commencement of production ("**Facility Ready Date**"). If the Preliminary Period extends [*], the Parties will negotiate in good faith the API Purchase Price for the remaining Preliminary Period in accordance with the same procedures set forth in Section 2.4 below. Thus, SPL is committing to the API Purchase Price for [*], but acknowledges that Cantex is only making a [*] purchase commitment at this time.

2.3 Negotiation of Facility Expansion. The Parties recognize that by the end of [*], Cantex's requirements for API may exceed SPL's current capacity to manufacture and supply API. At any time, Cantex may request that SPL increase its capacity to manufacture and supply API to Cantex to a commercially reasonable capacity given likely demand for the Product, keeping in mind that it will likely take no less than [*] to build and qualify such new facility. Upon such a request, the Parties shall enter into a negotiation in good faith to discuss the terms and conditions for such an expansion (a "**Facility Expansion**"). In addition, the Parties will negotiate in good faith such other matters as are commercially reasonable in connection with the Facility Expansion. Subject to reaching a mutual agreement, the Parties may enter into a Facility Expansion agreement detailing the manner in which SPL shall increase its API manufacturing capacity and supply such API to Cantex. Cantex may elect to undertake the Facility Expansion if Cantex has reasonably concluded that FDA Approval is likely to be forthcoming in the reasonably foreseeable future. In such event, the Parties will discuss in good faith the scope of the Facility Expansion, its design, the requisite capital equipment and similar items necessary to complete a Facility Expansion, including a budget and reasonable "take or pay" arrangement with respect to API that is producible from such Facility Expansion. Cantex may require SPL to pay for the Facility Expansion once FDA Approval of a Product is received, provided that the volume of API to be purchased from the Facility Expansion is an amount reasonably sufficient to allow SPL to amortize the costs of the Facility Expansion over a reasonable period. If Cantex requests that SPL pay for the Facility Expansion before FDA Approval is received, SPL shall have the right to refuse to pay for the Facility Expansion and in such case, Cantex may terminate this Agreement as its sole recourse; provided, however, that neither Party shall be prohibited from pursuing available remedies at law or equity in connection with the other Party's breach of any other provision of this Agreement. In the event Cantex determines to undertake a Facility Expansion and the Parties are unable to reach agreement on all terms of the Facility Expansion, the Parties will submit the open issues to binding arbitration in accordance with this Section 2.3 and Section 12.3. SPL may not refuse to undertake a Facility Expansion if Cantex is funding the Facility Expansion or if Facility Expansion is to be undertaken after FDA Approval is received. The Facility Expansion shall not exceed in size and scope the facility required to produce the reasonably expected requirements of API for the [*] period following the completion of the Facility Expansion, except by mutual agreement of the Parties.

The "Arbitrator," under this Section 2.3 shall be a party with expertise in the construction of facilities for the production of biologic pharmaceutical products. The Arbitrator for the Facility Expansion will not determine API Purchase Price for the period following the Facility Expansion.

2.4 Commercial Pricing and Quantity. For the period of the Term following the Preliminary Period, the API Purchase Price shall be determined and subject to adjustment in accordance with this Section 2.4.

(a) At least four (4) months prior to the date the Parties agree that commercial scale production will begin from the Facility Expansion, and, thereafter, at least four (4) months prior to the expiration of the [*] period following the date on which the API Purchase Price is agreed with respect to the Facility Ready Date and on a biennial basis thereafter during the remainder of the Term (in each case the "**Price Negotiation Period**"), the Parties shall discuss changes to the API Purchase Price and shall reach agreement in good faith on a revised API Purchase Price for the succeeding [*] period (the "[*] **Period**"). The negotiation of the API Purchase Price shall be based on factors such as market conditions with respect to the supply chain and taking into account the increased volumes and efficiencies made available by the Facility Expansion as well as the Party who has funded the Facility Expansion, the amortization and depreciation of the Facility Expansion, other capital expenditures and costs needed to commission start-up and operate the facility.

(b) During the first two (2) months of the Price Negotiation Period, either of the Parties may request that the Chief Executive Officers of each of the Parties participate in the negotiation process. During the Price Negotiation Period, the Parties will negotiate in good faith a commercially reasonable API Purchase Price for the succeeding [*] Period. During the Term of this Agreement, the commercially reasonable API Purchase Price will not exceed the API Purchase Price for the Preliminary Period in the absence of a catastrophic disruption to the heparin market, and then only during the period that Raw Material costs are elevated by such catastrophic disruption.

(c) During the last two (2) months of the Price Negotiation Period, in the event the Parties have not reached agreement on the API Purchase Price, either Party may request arbitration for the API Purchase Price for the succeeding [*] Period by providing written notice of arbitration to the other Party. Within ten (10) days of receipt of such notice the Parties shall appoint as Arbitrator an independent accounting firm of regional or national stature who shall make the determination of the API Purchase Price for the succeeding [*] Period pursuant to the procedure set forth below. The Arbitrator shall be a firm that has not provided any services to either Party or their Affiliates for at least a three-year period prior to the arbitration. Such Arbitrator shall as a condition of being appointed arbitrator execute and deliver such commercially reasonable nondisclosure agreements as may be required by the Parties. In the event the Parties are unable to agree upon such Arbitrator, the Arbitrator will be appointed by the Chief Judge of Federal District Court of the Western District of Wisconsin. Each of the Parties shall submit in writing to the Arbitrator such Party's final and best API Purchase Price for the [*] Period, and the Arbitrator may select in its determination an API Purchase Price that is not less than the API Purchase Price submitted by Cantex, nor more than the API Purchase Price submitted by SPL. Each of the Parties shall also submit in writing to the Arbitrator, the rationale of such Party for API Purchase Price it proposes, as well as data and other information as the Arbitrator may request. SPL may provide costing information to the Arbitrator, but such information shall be kept in confidence, and shall not be provided to Cantex. The Arbitrator shall make such determination as expeditiously as

possible, and such determination shall be final and binding upon the Parties for the succeeding [*] Period. SPL may not withhold deliveries of API during the Price Negotiation Period, and Cantex will timely pay to SPL an amount equal to the price that had been in effect for the prior [*] Period in the event the arbitration process runs into the next succeeding [*] Period. If the final determination is received after the commencement of the [*] Period, the amount to be paid shall be "trued up" if necessary, and an immediate payment shall be made from Cantex to SPL if the API Purchase Price is higher than that paid to date by Cantex; or a credit shall be provided to Cantex from SPL in the event the API Purchase Price has been higher than the new API Purchase Price during the succeeding [*] Period.

(d) In determining the API Purchase Price for each succeeding [*] Period, the Parties shall take into account changes in market conditions, Raw Material Costs, manufacturing efficiencies, the amortization and depreciation of Facility Expansion Costs paid by SPL, other capital expenditures needed by SPL in connection with the Facility Expansion and profit margin percentages during the Preliminary Period. Thus, by way of example, if SPL funds some or all of the Facility Expansion, the API Purchase Price may be higher than if it does not fund any of the Facility Expansion and if Cantex funds the Facility Expansion, the API Purchase Price may be lower. Changes in Raw Material Costs shall not be taken into consideration unless Raw Material Costs are plus or minus [*] of Raw Material Costs as of the date of this Agreement absent a catastrophic disruption to the heparin market as described above. For purposes of determining "Raw Material Costs," SPL shall detail the Raw Material Costs for producing the API as of the date of the Agreement in auditable form. In the event there is a change in the Raw Material Costs above or below the benchmark as of the date of the Agreement, SPL shall notify Cantex of such change, and will allow audit of such benchmark and change by Cantex's independent firm of certified public accountants, who shall not provide any information to Cantex other than the percentage by which Raw Material Costs are above or below the benchmark. Any determination dispute will be subject to arbitration in accordance with Section 2.4.

2.5 Purchase Orders and Acceptance.

(a) Purchase Orders. Immediately after the execution of this Agreement, Cantex shall issue a purchase order for [*] of API satisfying Cantex's purchase obligations for the first twelve (12) months of the Term, [*] of which is to be delivered in 2015.]. For the remainder of the Preliminary Period Cantex shall have the right, but not the obligation to issue purchase orders for API up to a maximum of [*] per year. [*] Three (3) months prior to the end of each year of this Agreement, Cantex shall provide SPL with a notice for the subsequent year of the Term that it intends to purchase up to a maximum of [*] per year of API from SPL (or such additional maximum amount following the Facility Expansion) by issuing a binding purchase order to SPL.

(b) Acceptance. SPL agrees to fulfill the purchase orders submitted by Cantex in accordance with Section 2.5(a) above. SPL shall provide Cantex with a written acknowledgement of its receipt of each Cantex purchase order together with the date on which production of the API will commence (which shall be no later than ten (10) days from the date of receipt of the purchase order).

2.6 Delivery. All delivery and transit arrangements for the API shall be Ex-Works SPL's Waunakee Facility to the location as stated in the purchase order and within five (5) business days of the delivery date specified in the purchase order. Such delivery date will be a reasonable date following the receipt of the purchase order in order to allow SPL adequate time to manufacture the API. Shipping shall be conducted in accordance with those controlled environment and other shipping conditions as are reasonably specified by Cantex in the purchase orders or otherwise in writing. SPL shall invoice Cantex for any actual reasonable out-of-pocket shipping costs (including insurance costs) paid by SPL pursuant to the foregoing arrangement as a separate line item on the invoice, to the extent such costs are not already taken into account. Title to the API shall pass to Cantex upon delivery to the carrier at SPL's Waunakee Facility. SPL agrees that Cantex may specify that the delivered API be stored in a SPL cGMP-qualified storage facility, the cost of which storage shall be mutually agreed between the Parties and paid by Cantex. For the sake of clarity, title to the stored API shall pass to Cantex when the instructions are received by SPL to store the product; it will also be invoiced at that time. With respect to the delivery of each batch of API, Cantex may elect to have SPL store such batch until such time that Cantex elects to take delivery or otherwise notifies SPL in writing to deliver such API to a party designated by Cantex. With respect to the storage of API, Cantex and SPL shall mutually agree on a fee for such storage and SPL shall store the API in accordance with Cantex's storage guidelines and other customary terms associated with the storage of third party-owned products.

2.7 Documentation.

(a) Certificates. Each shipment of API shall be accompanied by a "**Certificate of Analysis**" confirming that API delivered is Conforming API pursuant to Section 4.1.

(b) Shipping Documentation. Each shipment of API shall be accompanied by commercially appropriate shipping documentation (including bills of lading), which shall, subject to the provisions of the Quality Agreement, (i) identify the shipment and batch numbers comprised in the shipment, (ii) state any purchase order number for the shipment that has been provided by Cantex, and (iii) show the destination where such shipment is being sent.

2.8 Exclusivity. SPL acknowledges and agrees that the production of the API involves SPL's access to and use of confidential and proprietary Cantex Intellectual Property [*]. Accordingly, SPL agrees as follows:

(a) throughout the Term, SPL and its Affiliates shall not directly or indirectly in the Territory engage in the development, manufacture, commercialization, sale or distribution (or assist in the development, manufacture, commercialization, sale or distribution) of a Competitive Product whether for itself or for any Affiliate or Third Party other than Cantex;

(b) following the expiration or termination of this Agreement, SPL and its Affiliates shall not and are perpetually excluded from directly or indirectly in the Territory engaging in the development, manufacture, commercialization, sale or distribution (or assist in the development, manufacture, commercialization, sale or distribution) of a Competitive Product that contains or makes use of any Cantex Intellectual Property (including any Cantex Confidential Information) whether for itself or for any Affiliate or Third Party; and

(c) following expiration or termination of this Agreement, and for the Applicable Period (as defined below), SPL and its Affiliates shall not directly or indirectly in the Territory engage in the development, manufacture, commercialization, sale or distribution (or assist in the development, manufacture, commercialization, sale or distribution) of any active pharmaceutical ingredient or product containing [*] and which do not make use of Cantex Intellectual Property or Cantex Confidential Information for itself or any Third Party.

(d) The "**Applicable Period**" shall have the following meaning:

(i) [*] following the expiration of the Term of this Agreement in accordance with Section 11.1;

(ii) the longer of [a] the remaining unexpired Term of this Agreement plus [*] or [b] [*] from the date of termination, in the event Cantex terminates this Agreement under Section 11.2(b)(i) or Section 11.2(c);

(iii) [*] from the date of termination, in the event Cantex terminates this Agreement as a result of an Event of Force Majeure affecting the ability of SPL to perform this Agreement (in which the case the exclusivity requirement in Section 2.9 shall not apply); provided, however, in the event SPL [a] cures the Event of Force Majeure within [*] of the date of such termination and [b] can demonstrate to Cantex's reasonable satisfaction that SPL is capable of supplying at least [*] of Cantex's requirements, then the Agreement shall be deemed to continue (provided however, that the exclusivity requirement in Section 2.9 shall be suspended with respect to any reasonable supply agreement or arrangement Cantex may have in effect due to the Event of Force Majeure causing the termination) and the exclusivity provisions of this Section 2.8 shall continue to apply for the remaining Term of this Agreement and beyond pursuant to the various provisions of this Section 2.8;

(iv) [*] if the Agreement terminates for failure to obtain FDA approval or abandonment in accordance with the provisions of Section 11.2(a)(iii);

(v) [*] from the date of the material breach in the event SPL terminates this Agreement upon a material breach by Cantex, as set forth in Section 11.2(a), subject to the cure rights described in Section 11.2(a)(i) in which case, upon a timely cure by Cantex, the Agreement shall be deemed to continue and the exclusivity provisions of this Section 2.8 shall continue to apply for the remaining Term of this Agreement and beyond pursuant to the various provisions of this Section 2.8;

(vi) [*] in the event SPL terminates this Agreement upon the insolvency of Cantex as set forth in Section 11.2(c);

(vii) [*] in the event Cantex terminates the Agreement upon SPL's determination not to pay for a Facility Expansion prior to FDA approval as described in Section 2.3.

(viii) [*] in the event SPL terminates this Agreement as a result of an Event of Force Majeure affecting the ability of Cantex to perform its obligations under this

Agreement; provided, however, if Cantex cures the Event of Force Majeure within [*] of the effective date of SPL's termination, Cantex may request that SPL continue as the exclusive supplier in which case, the Agreement shall be deemed to continue and the exclusivity provisions of this Section 2.8 shall continue to apply for the remaining Term of this Agreement and beyond pursuant to the various provisions of this Section 2.8;

2.9 [*].

2.10 Competitive Product. For purposes of this Agreement, the term "**Competitive Product**" means any active pharmaceutical ingredient or product (i) [*] or (ii) [*].

ARTICLE III

PAYMENT

3.1 Payment Terms. Payment of all amounts shall be in U.S. Dollars, by a Cantex company check or wire transfer of immediately available funds to the financial institution, account number and account party's name designated in writing by SPL as the place of payment. SPL shall invoice Cantex against the deliveries of API ordered in connection with the purchase orders submitted in accordance with Section 2.5. Except as otherwise permitted herein, Cantex shall pay SPL within thirty (30) days of the date on which Cantex receives the invoice, which invoice shall not be issued earlier than upon the delivery date of the API to Cantex; notwithstanding the foregoing, if SPL stores API for Cantex, the delivery date will be deemed to be the date SPL places such API in storage. In the event SPL invoices remain unpaid after thirty (30) days from the date of Cantex's receipt of the invoice, other than for reasons of an invoice that is being disputed by Cantex in good faith and in writing (and only as to such portion of an invoice that is in dispute), then the amount outstanding under that invoice shall bear interest at a rate per annum equal to the highest rate permitted under New York law.

3.2 Taxes. Cantex shall be responsible for paying all federal, state and local sales, use, consumption, value added or excise taxes, custom charges, tariffs, duties and other similar assessments and taxes which may be imposed by any Governmental Authority upon SPL (other than income taxes) as a purchaser of the API on an Ex Works basis **("Transfer Taxes")** in connection with this Agreement.

ARTICLE IV

QUALITY OF PRODUCTS

4.1 Quality Agreement. The Parties agree to execute, simultaneously with this Agreement, an agreement which shall specify the roles and responsibilities of Cantex and SPL with respect to testing, storage, release, cGMP, regulatory and other quality assurance requirements relating to the manufacture, supply and shipment of API by SPL under this Agreement (the "**Quality Agreement**") which shall be attached hereto as Exhibit B.

4.2 Qualification of Sources. All procurement of raw materials for the manufacture of the API supplied hereunder shall comply in all material respects with the Quality Agreement.

SPL shall comply with all Regulatory Requirements pertaining to procurement of raw materials for the API, including any testing or documentation required.

4.3 Storage and Use of API. SPL shall ensure that the storage of all API is in accordance with the Quality Agreement and Regulatory Requirements. Cantex shall be responsible for storage of the API which has been shipped to Cantex pursuant to Article II, but may request that SPL provide proper storage for delivered shipments at SPL qualified facilities (at Cantex's expense) until such time that Cantex requires use of the API. Cantex will be responsible for any shelf life issues with respect to stored API.

4.4 API Testing and Release. SPL shall perform in-process and product release testing and manage sub-contracting testing lab, review and release of the API, and issue a Certificate of Analysis for the API in accordance with Section 2.7(a) and in accordance with the Quality Agreement.

4.5 Approval of Subcontracting. Except as contemplated by this Agreement, SPL shall not have the right to subcontract, sublicense or otherwise delegate all or any portion of its obligations under this Agreement without Cantex's prior written consent, which shall not be unreasonably withheld; provided, however, that SPL may subcontract testing and analytical services only to (a) its Affiliates located in North America and (b) Third Parties located in North America, in each case without the consent of, but with prior notice to Cantex and provided further that such Affiliates have agreed in writing to Cantex to be bound by the exclusivity and confidentiality requirements set forth in this Agreement and Third Parties have agreed to be bound by the confidentiality and intellectual property ownership requirements of this Agreement. To the extent that use of a subcontractor is permitted under this Section 4.5, SPL shall (i) fully qualify each such subcontractor and (ii) ensure that all such approved subcontractors comply with the provisions of this Agreement to the extent applicable thereto. Notwithstanding SPL's use of a subcontractor, subject to the limitations on liability set forth in this Agreement, SPL shall remain primarily responsible and liable to Cantex with respect to each subcontractor's breach of its confidentiality obligations concerning Cantex Confidential Information or failure to perform its obligations in a manner consistent with the terms of this Agreement.

4.6 Product Warranty. SPL represents and warrants to Cantex that all API manufactured hereunder will be manufactured, labeled, packaged, stored, tested, documented, released and shipped in accordance with the API Specifications, SPL's responsibilities under the Quality Agreement, applicable Regulatory Requirements, this Agreement and all applicable Laws. Such API meeting the requirements of the preceding sentence shall be deemed "**Conforming API**".

4.7 Non-Conforming API.

(a) Cantex shall have the right at any time following delivery of the API to test the API and determine whether the API is Conforming API. During shipment and following receipt of the API by Cantex, Cantex shall cause the API to be properly maintained and stored. If, Cantex learns that any API delivered under this Agreement are not Conforming API by reason of non-compliance with the API Specifications, Quality Agreement or the Regulatory Requirements, then

Cantex shall notify SPL in writing of such discovered defect promptly after such noncompliance is confirmed. Cantex shall notify SPL of such nonconformance within a reasonable time after such API is delivered to Cantex.

(b) If Cantex notifies SPL that the API received are not Conforming API, then SPL shall be offered a reasonable opportunity to examine the evidence purporting to show why such API are or were non-Conforming API and to inspect or test such API. In the event of any dispute as to whether any API are or were non-Conforming API, and rightfully rejected by Cantex pursuant to the above provisions relating thereto, the matter shall be referred to an independent testing organization mutually acceptable to the Parties to resolve the dispute. The fees and expenses of such organization shall be paid by the Party in error.

4.8 Rights and Remedies for Delivery of Non-Conforming API. With respect to any API that are non-Conforming API, as agreed by the Parties or determined by an independent testing organization pursuant to Section 4.7(b), SPL shall, at Cantex's option, (a) replace the non-Conforming API at SPL's sole cost and expense or (b) provide a credit to Cantex with respect to such non-Conforming API. In the event Cantex purchases replacement API from another party (which shall not constitute a breach of Cantex's exclusivity obligations under Section 2.9), in addition to refunding the cost of the API charged by SPL, SPL shall be responsible for paying to Cantex the reasonable costs of cover (i.e., the difference between the price of the API charged to Cantex by SPL for the non-Conforming API and the reasonable price for the replacement API). Following replacement, reimbursement in full (including such reasonable costs of cover) with respect to the non-Conforming API, the non-Conforming API shall be owned by and available to SPL for pick-up at SPL's expense. SPL shall destroy all non-Conforming API and shall not use such non-Conforming API for any commercial purpose. Cantex shall have the right to retain or dispose of any non-Conforming API that is not collected by SPL within thirty (30) days of the determination that the API is non-Conforming API.

ARTICLE V

RECORDS

5.1 Records Retention. With respect to the API, SPL shall generate and maintain complete and accurate records (including files, certificates and authorizations) necessary to evidence compliance with this Agreement, the Quality Agreement, applicable Laws, Regulatory Requirements and other requirements of applicable Governmental Authorities, including, where necessary, available sourcing data, development reports, batch records, quality control and laboratory testing, and any other data reasonably associated with ascertaining the quality and origin thereof. All such records, and all samples required to be maintained under this Agreement, shall be securely maintained for a period of not less than seven (7) years from the date of release of each shipment of API in accordance with the provisions of the Quality Agreement and Regulatory Requirements.

5.2 Availability. Upon the reasonable request of Cantex , SPL shall make relevant documents available to Cantex for inspection on site, including, but not limited to the batch records.

All such documents and records shall be considered "**Confidential Information**" subject to the Confidentiality Agreement in effect between the Parties.

ARTICLE VI

REGULATORY MATTERS

6.1 Permits. SPL shall obtain and maintain in good order, at its sole cost and expense, such governmental registrations, permits and licenses as are required by Governmental Authorities and Regulatory Requirements in order for SPL to perform all of its obligations under this Agreement (including any registrations granted by the FDA and any comparable registrations and/or licenses granted by any other Regulatory Authority) (each, a "**Permit**"**)**, for so long and insofar as is necessary to permit SPL to perform any activity contemplated hereunder.

6.2 Compliance with cGMPs; Monitoring of Records. Throughout the Term, SPL shall ensure that the manufacturing of the API and the performance of SPL's services hereunder comply with cGMPs, as applicable, including through the establishment and implementation of such operating procedures and the training of personnel as are required to assure such compliance. Throughout the Term and for so long thereafter as is reasonably necessary, SPL also shall monitor and maintain appropriate records with respect to its compliance with cGMPs with respect to the Product and permit Cantex access to such records in accordance with Section 5.2 above with respect to the Product.

6.3 Regulatory Communications and Correspondence. Each Party shall promptly notify the other Party of all such Party's communications from and to the FDA or other Regulatory Authorities which may impact or change the manufacturing or processing activities performed by SPL hereunder, or affect the ability of SPL to comply with its obligations under this Agreement. In all cases involving changes to the manner in which the API is manufactured or processed, the terms set forth herein and in the Quality Agreement shall apply with respect to any required modification to the manufacturing process.

ARTICLE VII

INTELLECTUAL PROPERTY RIGHTS

7.1 SPL IP. SPL has decades of experience in the development, testing and production of heparin and its derivatives. All Intellectual Property Rights developed by or on behalf of SPL and related to the procurement of the appropriate raw material, the formulas, formulations, specifications, production methods and analytical methods for heparin and its derivatives (excluding ODSH, the API and Products and not including those constituting improvements to or derivatives of Cantex Intellectual Property) are proprietary to SPL and are SPL Intellectual Property. All improvements to SPL Intellectual Property belong to SPL.

7.2 Cantex IP. All Intellectual Property Rights including the formulas, formulations, specifications, production methods and analytical methods for the API and Products which have been developed by, or on behalf of, Cantex and its predecessor comprise Cantex Intellectual Property and are owned by Cantex. Cantex Intellectual Property also includes the [*] analytical method for use with the API and Products and the specification for [*] by which the lots of Heparin

are selected to produce the API and Products. All improvements to or derivatives of the API and the Product formulas, formulations, specifications, production methods analytical methods or other Cantex Intellectual Property (but not including those constituting improvements to or derivatives of SPL Intellectual Property), are proprietary to Cantex and are Cantex Intellectual Property, and to the extent that SPL has participated in the development of such improvements or derivatives, SPL shall promptly disclose such information to Cantex in writing.

7.3 Claims. SPL and its Affiliates shall make no claims with respect to the Cantex Intellectual Property and will have no right thereto. Cantex shall make no claims with respect to the SPL Intellectual Property, and will have no right thereto.

7.4 Licenses; Assistance.

(a) In order to perform its obligations under this Agreement, SPL will need to use the Cantex Intellectual Property. Cantex hereby grants to SPL a limited, royalty free, terminable, revocable, non-exclusive, non-transferable, non-sublicensable license to the Cantex Intellectual Property solely as may be necessary to allow SPL to perform its manufacturing and related obligations under this Agreement. Such license shall terminate upon the termination of this Agreement.

(b) SPL hereby consents, during the term of this Agreement, to Cantex's use of Heparin for the manufacture and commercialization of the API and the Product. Such consent terminates upon the termination of this Agreement for any reason; provided however, that such consent shall remain in effect with respect to existing API and Product and work in process.

(c) Throughout the Term, SPL agrees to assist Cantex (at Cantex's expense) with any testing reasonably requested by Cantex in connection with obtaining Regulatory Approval of the API or Products from any Regulatory Authority.

7.1 Assignment to Cantex. Regarding Cantex Intellectual Property Rights, SPL shall assume all rights to employee inventions in accordance with applicable laws on employee inventions and hereby assigns to Cantex, in advance as of the Effective Date, title to any and all Cantex Intellectual Property Rights developed by SPL and its Affiliates, employees and subcontractors. To the extent that an assignment of the Cantex Intellectual Property Rights should not be possible under the applicable law, SPL shall assign to Cantex such Cantex Intellectual Property Rights upon their coming into existence, and Cantex shall accept such assignment. To the extent that an assignment of Cantex Intellectual Property Rights should not be possible at all under the applicable law, SPL, in advance as of the Effective Date, grants to Cantex an exclusive, perpetual, irrevocable, worldwide, transferable, fully paid-up license, which includes the right to grant sub-licenses and permit sub-sublicenses, to use and commercialize such Cantex Intellectual Property Rights in any way. Cantex herewith accepts such grant of license. The Parties acknowledge and agree that SPL shall be solely responsible for paying its employees any remuneration due under applicable law on employee inventions in connection with Cantex Intellectual Property Rights developed by such employees and SPL Intellectual Property Rights. Should any such claims for remuneration be directed against Cantex, its Affiliates and/or sub-

licensees, Cantex shall immediately notify SPL of such claims, tender the defense of such claims to SPL and SPL will indemnify Cantex with respect to such claims as set forth and subject to the limitations set forth in Article X below.

ARTICLE VIII

PUBLICITY; CONFIDENTIALITY

8.1 Publicity. Except as required by Law or the standards of any securities regulatory authority, including the SEC, NASDAQ and NYSE, SPL and Cantex may not make any official press release, announcement or other formal publicity relating to the terms of this Agreement or transactions that are the subject of this Agreement without first obtaining in each case the prior written consent of Cantex or SPL, respectively (which consent may not be unreasonably withheld). If any Party is required to file this Agreement with the SEC or another applicable securities regulatory authority, such Party must seek confidential treatment for any provisions of this Agreement that any Party believes would disclose trade secrets or confidential commercial or financial information and therefore, in such case, the Parties shall coordinate such filing efforts. Except as required by Law or the standards of any securities regulatory authority, SPL and Cantex may not use the name or trademarks of Cantex or SPL, respectively, or any Representative thereof or any adaptation thereof without the prior written approval of Cantex or SPL, respectively.

8.2 Confidentiality. The Parties hereby confirm and agree to remain to be bound by the terms of the Mutual Confidentiality Agreement and attached hereto as Exhibit C ("**Confidentiality Agreement**") and notwithstanding any provisions concerning termination set forth therein, such Confidentiality Agreement shall remain in effect throughout the Term of this Agreement and shall survive the termination of this Agreement without limitation.

ARTICLE IX

REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties of Cantex. Cantex hereby represents and warrants to SPL as follows:

(a) Cantex is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Cantex is duly qualified to do business and is in good standing in each jurisdiction where its ownership or leasing of property or the conduct of its business requires it to be so qualified.

(b) The execution, delivery, and performance of this Agreement by Cantex has been duly authorized by all requisite corporate action and does not require any further action or approval.

(c) Cantex has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

(d) The execution, delivery, and performance by Cantex of this Agreement and its compliance with the provisions of this Agreement 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) any other agreement to which it is a party; (ii) the provisions of its organizational documents; or (iii) any Judgment, writ, or decree of any court or Governmental Authority entered against it or by which any of its property is bound.

(e) Cantex has obtained each consent, approval or authorization of or has provided any notice, declaration, filing or registration with, any Governmental or Regulatory Authority required for the execution, delivery and performance of this Agreement, and the execution, delivery and performance of this Agreement will not violate any Law, rule or regulation applicable to Cantex .

(f) This Agreement has been duly executed and delivered and constitutes Cantex's legal, valid and binding obligation, enforceable against Cantex in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles.

(g) Cantex will not use in any capacity the services of any persons debarred or convicted under 21 U.S.C. § 335(a) or 335(b) in connection with the performance of this Agreement. Cantex does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Act.

(h) Cantex shall comply with all Laws, rules and regulations relating to its activities under this Agreement.

(i) As of the Effective Date, Cantex is not aware of any third party Intellectual Property Rights that will be infringed by the manufacture of the API, and Cantex will promptly inform SPL if it receives notice of any claim or potential claim relating to infringement or alleged infringement of any third party Intellectual Property Rights by virtue of the manufacture of API hereunder;

(j) Cantex warrants that it has ownership of the Cantex Intellectual Property described in Article VII.

9.2 Representations and Warranties of SPL. SPL represents and warrants to Cantex as follows:

(a) SPL is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. SPL is duly qualified to do business and is in good standing in each jurisdiction where its ownership or leasing of property or the conduct of its business requires it to be so qualified.

(b) The execution, delivery and performance by SPL of this Agreement have been duly authorized by all requisite limited liability company action and does not require any further action or approval.

(c) SPL has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

(d) The execution, delivery, and performance by SPL of this Agreement and its compliance with the provisions of this Agreement 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) any other agreement to which it is a party; (ii) the provisions of its organizational documents; or (iii) any Judgment, writ, or decree of any court or Governmental Authority entered against it or by which any of its property is bound.

(e) SPL has obtained each consent, approval or authorization of or has filed each notice, declaration, filing or registration with, any Governmental or Regulatory Authority required for the execution, delivery and performance of this Agreement, and the execution, delivery and performance of this Agreement will not violate any Law, rule or regulation applicable to SPL.

(f) This Agreement has been duly executed and delivered and constitutes SPL's legal, valid and binding obligation, enforceable against SPL in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles.

(g) SPL will not use in any capacity the services of any persons debarred or convicted under 21 U.S.C. § 335(a) or 335(b) in connection with the manufacture of the Products. SPL does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Act.

(h) SPL shall require that all subcontractors shall comply with all Laws, rules and regulations relating to its activities under this Agreement.

(i) As of the Effective Date, SPL is not aware of any third party Intellectual Property Rights that will be infringed by the manufacture of the API, and SPL will promptly inform Cantex if it receives notice of any claim or potential claim relating to infringement or alleged infringement of any third party Intellectual Property Rights by virtue of the manufacture of API hereunder;

(j) SPL will involve in the performance of the manufacturing services hereunder only those of its employees who have been previously informed in writing of their obligations under laws applicable to employee inventions to notify any inventions and/or improvements made in connection with the performance of the manufacturing services to their respective employer and to assign any rights to such inventions or improvements to such employer.

(k) SPL warrants that it has ownership of the SPL Intellectual Property described in Article VII.

9.3 Disclaimer of Warranties.

(a) THE WARRANTIES PROVIDED IN SECTION 9.1 ABOVE ARE THE EXCLUSIVE WARRANTIES GIVEN BY CANTEX TO SPL WITH RESPECT TO THE MATTERS SET FORTH HEREIN, AND ARE GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, GUARANTEES, CONDITIONS AND REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

(b) THE WARRANTIES PROVIDED IN SECTION 4.6 AND 9.2 ABOVE ARE THE EXCLUSIVE WARRANTIES GIVEN BY SPL TO CANTEX WITH RESPECT TO THE MATTERS SET FORTH HEREIN, AND ARE GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, GUARANTEES, CONDITIONS AND REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE X

INDEMNIFICATION

10.1 Indemnification by SPL . SPL shall indemnify, defend and hold harmless Cantex and its Affiliates and their respective officers, managers, equity holders, employees, agents and representatives (each a "**Cantex Indemnified Party**") from and against any and all claims, actions, suits, proceedings, losses, liabilities, damages, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees) (collectively, "**Losses**") incurred, sustained or suffered by such Cantex Indemnified Party by reason of a Third Party claim arising out of or resulting from:

(a) any breach by SPL of any of its representations, warranties, covenants, undertakings or obligations under this Agreement; or

(b) any negligent or wrongful act or omission or misconduct by SPL or any of its Affiliates or any of their respective employees, subcontractors, representatives or agents in connection with the performance of SPL's obligations under this Agreement; or

(c) any infringement or alleged infringement or breach of any Intellectual Property Rights of a Third Party caused by use of the SPL Intellectual Property Rights by SPL or its subcontractors in the performance of the manufacturing services hereunder; or

(d) any recalls, seizures, product liability claims or claims of personal injury relating to the API or any Product to the extent such claim is based (i) on SPL's negligence or intentional wrongdoing in manufacturing the API or in performing any other obligations under this Agreement, or (ii) on the breach of any of SPL's warranties under Section 4.6 or Section 9.2 hereunder;

provided, however, that SPL shall not be required to indemnify any Cantex Indemnified Party with respect to any such Losses to the extent that Cantex is obligated to indemnify SPL under Section 10.2.

10.2 Indemnification by Cantex . Cantex shall indemnify, defend and hold harmless SPL and its Affiliates and their respective officers, managers, equity holders, employees, agents and representatives (each a "**SPL Indemnified Party**") from and against any and all Losses incurred, sustained or suffered by such SPL Indemnified Party by reason of a Third Party claim arising out of or resulting from:

(a) any breach by Cantex of any of its representations, warranties, covenants, undertakings or obligations under this Agreement; or

(b) any negligent or wrongful act or omission or misconduct by Cantex or any of its employees, subcontractors, representatives or agents in connection with the performance of their obligations under this Agreement; or

(c) any recalls, seizures, product liability claims or claims of personal injury or property damage arising from the manufacture, packaging (including labeling), use, sale or distribution of any Products by Cantex or any of its employees, subcontractors, representatives, customers or agents;

(d) any infringement or alleged infringement or breach of any Intellectual Property Rights of a Third Party caused by use of Cantex Intellectual Property Rights.

provided, however, that Cantex shall not be required to indemnify any SPL Indemnified Party with respect to any such Losses to the extent that SPL is obligated to indemnify Cantex under Section 10.1.

10.3 Procedure for Indemnification. Each Party seeking to be reimbursed, indemnified, defended, and/or held harmless under Sections 10.1 or 10.2 (each, an "**Indemnitee**") shall provide the Party obligated to indemnify such Indemnitee (the "**Indemnitor**") with prompt, written notice of any claim, suit, demand, or other action for which such Indemnitee seeks to be reimbursed, indemnified, defended, and/or held harmless (each, a "**Claim**"), which notice shall include a reasonable identification of the alleged facts giving rise to such Claim. The failure to give such notice shall not relieve the Indemnitor from any liability that it may have to Indemnitee, except to the extent that the Indemnitor's ability to defend such claim or suit is materially prejudiced by such failure to give notice. Each Indemnitee shall have the right to participate in the defense of any Claim for which Indemnitee seeks to be reimbursed, indemnified, defended, or held harmless, by using attorneys of such Indemnitee's choice, at such Indemnitee's expense. The Indemnitor shall not enter into any settlement agreement, which would materially adversely affect the rights or obligations of the Indemnitee under this Agreement without the Indemnitee's prior written consent.

10.4 Offset of Insurance Proceeds. Any indemnification hereunder shall be made net of any insurance proceeds recovered by the Indemnitee; provided, that, if, following the payment

to the Indemnitee of any amount under Article X, such Indemnitee recovers any insurance proceeds in respect of the claim for which such indemnification payment was made, such Indemnitee shall promptly pay an amount equal to the amount of such insurance proceeds (but not exceeding the amount of such indemnification payment from the Indemnitee) to the Indemnitor.

10.5 Required Insurance. Without limiting their obligations hereunder, both Parties shall maintain at their individual sole expense, commencing with the Effective Date and continuing throughout the Term and any renewals thereof, sufficient insurance coverage to satisfy their obligations hereunder. Without derogating from the foregoing, this shall include, at minimum, the following insurance: (a) commercial general liability insurance, including broad form contractual liability and personal injury coverage, with limits of not less than [*] per occurrence and [*] annual aggregate, general liability umbrella with a coverage limit of not less than [*]; (b) product liability insurance with a coverage limit of not less than [*] per occurrence and [*] annual aggregate. The required limits for general liability and product liability may be satisfied through a combination of primary and umbrella coverage. In the event that the Product is approved by the FDA and is commercialized, Cantex shall obtain customary product liability coverage to mitigate the additional risk of commercial distribution. Both Parties agree to provide 60 days' notice of cancellation or non-renewal of required insurance. Prior to the performance of any activities under this Agreement, each Party shall provide the other with a certificate of insurance evidencing its respective insurance coverage.

10.6 Limitation of Liability. EXCEPT WITH RESPECT TO (A) EACH PARTY'S INDEMNIFICATION OBLIGATIONS PURSUANT TO ARTICLE X, (B) A BREACH OF SPL's OBLIGATIONS UNDER SECTION 2.8, (C) A BREACH OF CANTEX'S OBLIGATIONS UNDER SECTION 2.9 AND (D) A BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE VIII, NEITHER PARTY SHALL BE LIABLE WITH RESPECT TO ANY CLAIM RELATED TO THIS AGREEMENT FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES, INCLUDING ANY LOSS OF INCOME, LOSS OF PROFITS, COSTS OF SUBSTITUTION, COSTS OF COVER EXCEPT AS SET FORTH IN SECTION 4.8 OR INCREASED CAPITAL COSTS, REGARDLESS OF THE FORM OR NATURE OF ACTION, WHETHER IN CONTRACT, BREACH OF WARRANTY, STRICT LIABILITY, EQUITY, INDEMNITY, NEGLIGENCE, INTENTIONAL CONDUCT, TORT OR OTHERWISE, EVEN IF SUCH DAMAGES WERE FORESEEABLE OR IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE XI

TERM AND TERMINATION

11.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with the terms and conditions of this Agreement, shall continue in effect for [*].

11.2 Grounds for Termination.

(a) Termination by SPL. This Agreement may be terminated by SPL:

(i) Cantex has breached any of its material obligations under this Agreement, provided however, that termination with respect to those breaches that are capable of being cured shall be subject to a cure period of ninety (90) days of written notice of the breach provided by SPL, and provided further, if a breach capable of being cured by Cantex is not curable within ninety (90) days, this Agreement shall remain in effect and shall not terminate as long as Cantex is diligently curing such breach as expeditiously as possible but not in excess of 120 days. Notwithstanding the foregoing, if a termination under this Section 11.2(a)(i) is in dispute by Cantex, then the cure period shall be extended during the resolution period of such dispute and if Cantex cures the breach during such period, the Agreement shall not terminate and SPL's obligations under Section 2.8 (in addition to its other obligations hereunder) shall remain in effect. Provided, however, in no event shall such cure period extend to beyond one hundred eighty (180) days from such notice.

(ii) upon forty-five (45) days' written notice if Cantex has breached a payment obligation under this Agreement, which is not then in dispute, and has not cured such breach within such forty-five (45) day period; or

(iii) upon forty-five (45) days written notice if (i) Cantex has not received FDA approval for the marketing and sale of any Product incorporating the API within [*] of the date of this Agreement and Cantex is Not Pursuing (as defined below) further any FDA approval for a Product or (ii) Cantex and its successors have abandoned (i.e., have determined to no longer sell) an approved Product. For purposes of this Section 11.2(a)(iii), "**Not Pursuing**" means a lack of activity by Cantex with FDA in the [*] prior to SPL's written notice to Cantex under this Section 11.2(a)(iii) respect to Product approval; provided however, that inactivity that is a result of waiting for an applicable response from FDA or other delay not caused by Cantex shall not be counted for purposes of the determining the [*].

(b) Termination by Cantex . This Agreement may be terminated by Cantex in the event that:

(i) SPL has breached any of its material obligations under this Agreement, provided however, that termination with respect to those breaches that are capable of being cured shall be subject to a cure period of ninety (90) days of written notice of the breach provided by Cantex, and provided further, if a breach capable of being cured by SPL is not curable within ninety (90) days, this Agreement shall remain in effect and shall not terminate as long as SPL is diligently curing such breach as expeditiously as possible but not in excess of one hundred twenty (120) days;

(ii) upon at least ninety (90) days' prior written notice to SPL, if the FDA withdraws Regulatory Approval or fails to grant Regulatory Approval for the Product when reasonably expected or Cantex reasonably believes that the FDA will take (or, as context requires, fail to take) any such action or if Cantex reasonably believes that clinical data or other indicators

will have an adverse impact on the commercial viability of the Product, provided that Cantex shall provide ninety (90) days' prior written notice to SPL; or

(iii) upon at least forty-five (45) days' written notice if SPL determines not to undertake a Facility Expansion prior to FDA approval as described in Section 2.3.

(c) Termination for Insolvency. Either Party may terminate this Agreement immediately in the event that the other Party becomes the subject of a voluntary or involuntary proceeding relating to insolvency, receivership, liquidation, or composition for the benefit of creditors.

(d) Termination Due to Force Majeure. Cantex may terminate this Agreement upon written notice to SPL in the event that an Event of Force Majeure prevents SPL from performing its obligations under this Agreement for a period of one hundred eighty (180) days or is reasonably expected to be prevented from performing its obligations hereunder for a period of at least one hundred eighty (180) days. SPL may terminate this Agreement upon written notice to Cantex in the event that an Event of Force Majeure prevents Cantex from performing its obligations under this Agreement for a period of one hundred eighty (180) days or is reasonably expected to be prevented from performing its obligations under this Agreement for a period of at least one hundred eighty 180 days.

(a) Termination and Cure of Material Breach. Notwithstanding the provisions of Section 11.1(b)(i) or (ii) or Section 11.2(b)(i), if either Party asserts (the "Nonbreaching Party") that the other Party (the "Breaching Party") is in material breach of this Agreement, and the Breaching Party disputes either that it is in breach or that the breach is material, the Breaching Party may submit the relevant issue(s) of breach or material to Dispute Resolution and binding arbitration pursuant to Section 12.3 of this Agreement by providing written notice thereof to the Nonbreaching Party. If the Arbitrator determines that a material breach has occurred, the Breaching Party shall have an additional period of sixty (60) days from the date of the Arbitrator's determination to cure such material breach before termination is effective; provided, however, if the breach is a failure to make payment, the Breaching Party shall have ten (10) days from the Arbitrator's payment to cure such breach. Neither Party may suspend performance under this Agreement while a matter is pending before the Arbitrator or is subject to Dispute Resolution. However, in the event of a payment dispute, Cantex shall pay to SPL in accordance with this Agreement all amounts that are not in dispute. The date that the material breach by Cantex or SPL occurred will be determined by the Arbitrator.

11.3 Effects of Termination.

(a) Rights and Obligations. Upon the termination of this Agreement for any reason whatsoever all further rights and obligations of the Parties shall cease, except that the Parties shall not be relieved of: (i) any obligations accruing before the effective date of termination or (ii) any other obligation hereunder which survives termination pursuant to the express provisions of this Agreement.

(b) Work in Process. Upon termination, and provided that SPL is not in material breach with respect to such purchase order, Cantex shall be obligated to purchase the API subject to an effective purchase order pursuant to terms set forth in this Agreement or pay the reasonable and documented Raw Material Costs (excluding the raw material costs associated with the production of [*] to the extent that SPL can use such [*] for other customers or products) incurred by SPL in preparing to fulfill such API order (if such amount is lower) if such Raw Material Costs have been incurred, but production has not yet commenced.

(c) Confidential Information. In any event of expiration or termination of this Agreement, any Confidential Information, documentation and possible reproductions as well as tools and other means provided or disclosed by the disclosing Party to the other Party and all copies thereof (in whatever form), shall be immediately returned to the disclosing Party or, upon the disclosing Party's request, destroyed and destruction certified to the Disclosing Party, except for a single copy of such Confidential Information or other documentation which may be retained for the other Party's legal records, provided that such copy shall be subject to the confidentiality, non-use and nondisclosure obligations under Article VIII hereof.

(d) Transition of Manufacturing. Upon termination of this Agreement, SPL shall provide such cooperation as reasonably requested by Cantex to transfer and transition the manufacturing of the API to a Third Party manufacturer. SPL's transition obligation shall not include any obligation to provide SPL Intellectual Property Rights to a Third Party. Thus, any transition services and technology transfer shall be limited to Cantex Intellectual Property Rights. SPL shall not be entitled payment with respect to such transition services, in the case of a termination by Cantex upon material breach by SPL or upon insolvency of SPL. SPL shall be entitled to commercially reasonable payments with respect to transition services in a termination by SPL or Cantex as a result of an event of Force Majeure. SPL shall be entitled to twice its normal charges for transition services provided in the material breach or insolvency of Cantex; and provided further, if Cantex is delinquent in payments to SPL, SPL shall not be required to commence or continue providing transition services unless Cantex pays SPL all amounts in arrears and remains current in payments to SPL. Provided, if after a Force Majeure event preventing the performance of SPL, Cantex reengages SPL to supply API as described in Section 2.8(b)(iii) above, SPL shall credit transition payments made to SPL by Cantex.

(e) Survival. Termination or expiration of this Agreement shall not affect the rights and obligations that may have accrued to either Party under this Agreement prior to the date of termination or expiration, or that, by their terms, expressly survive termination, including, without limitation Article I, Section 2.8, Section 2.10, Section 3.2, Section 4.3 (if API continues to be stored by SPL), the last sentence of Section 4.5, Sections 4.6, 4.7, 4.8, Article V, Section 6.2 (concerning record retention), Article VII, Article VIII, Section 9.3, Article X, Section 11.3, Article XII, the Confidentiality Agreement and Sections 7.4.1, 7.5.1, 8.4.5 and 8.5 of the Quality Agreement.

ARTICLE XII

MISCELLANEOUS

12.1 Force Majeure. No Party shall be responsible to the other under this Agreement for failure or delay in performing any obligations under this Agreement, other than payment obligations, due to factors beyond its reasonable control, including but not limited to war, terrorism, sabotage, revolution, riot or civil commotion, strikes, lock-outs, regulatory changes, changes in capital markets, intervention or failure of the government, failure of raw material supply, including that caused by animal disease, including the significant lack of availability or scarcity of animal or porcine mucosa, failure of supplies of power or fuel, prohibitions against imports or exports of Products or raw materials used for the Products, explosion, sabotage, fire, flood, natural disaster or act of God (each such factor, an **"Event of Force Majeure")**. Upon the occurrence of an Event of Force Majeure, the Party failing or delaying performance shall (a) promptly notify the other Party in writing, setting forth the nature of the occurrence, its expected duration, and how that Party's performance is affected, (b) use Commercially Reasonable Efforts to avoid, rectify or remove the Event of Force Majeure. Any Party subject to an Event of Force Majeure shall resume performing its obligations under this Agreement as soon as practicable following resolution of the Event of Force Majeure. Except as otherwise provided herein, if an Event of Force Majeure occurs, the affected Party shall be excused from performing and the time for performance shall be extended as long as that Party is unable to perform as a result of the Event of Force Majeure.

12.2 Governing Law. The Agreement shall be governed under the law of the State of New York, without regard to its principles of conflicts of laws.

12.3 Dispute Resolution.

(a) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement or the rights or obligations of the Parties hereunder (a "**Dispute**"), the Parties will use good faith efforts to resolve such Dispute amicably between themselves as contemplated herein before initiating legal proceedings with respect to such Dispute. Either Party may initiate such informal dispute resolution by sending written notice to the other Party setting forth in reasonable detail the nature of the dispute (the "**Dispute Notice**"). Within thirty (30) days after delivery of such Dispute Notice, senior representatives of each Party with authority to resolve such matter shall meet to negotiate in good faith a resolution to the Dispute. Any specific discussions and correspondence among the representatives of the Parties taking place for purposes of any negotiations or mediation hereunder shall be treated as Confidential Information developed for purposes of settlement, shall be exempt from discovery and production and shall not be admissible in any lawsuit without the concurrence of all Parties. However, any documents identified in, or provided with, such communications, which are not prepared for purposes of such negotiations or mediation are not so exempted and may, if otherwise admissible, be admitted in evidence in any arbitration or lawsuit.

(b) Arbitration. If a dispute cannot be resolved by the Parties within the timeframe as set forth in Section 12.3(a) above, which time may be extended by mutual consent of both Parties, then the dispute shall be determined by binding arbitration in accordance with the arbitration rules of the American Arbitration Association ("**Rules**") in force when the notice of

arbitration is submitted in accordance with these Rules. The arbitration shall be conducted in New York, New York, by a single arbitrator having relevant industry experience and knowledge. The arbitration proceedings shall be conducted in English. The Arbitrator shall not be empowered to award damages in excess of those permitted under the Agreement. The use of any alternative dispute resolution procedure will not be construed, under the doctrine of laches, waiver, or estoppel, to adversely affect the rights of either Party. Judgment on the arbitration award may be entered in any court of competent jurisdiction. The prevailing Party in any dispute arising out of or relating to this Agreement shall be entitled to reasonable attorneys' and arbitrators' fees and costs. All information relating to a dispute and subsequent mediation and/or arbitration hereunder shall be treated as Confidential Information.

(c) If there is a dispute under this Agreement, the Parties shall continue to fulfill their respective obligations under this Agreement unless specified otherwise in this Agreement.

(d) Notwithstanding the foregoing, the provisions of this paragraph will not limit or delay in any way either Party's right to seek preliminary injunctive or other equitable relief from any court having jurisdiction, whether or not such Party has pursued informal resolution or arbitration in accordance with this paragraph.

12.4 Assignment.

(a) Assignment. No Party may assign any of its rights or delegate any performance under this Agreement, without the prior written consent of the non-assigning Party, which shall not be unreasonably withheld. An event which results in a Change of Control of a Party shall not be deemed to be an assignment for purposes of this provision, and no rights shall arise upon a Change of Control except as set forth herein.

(b) Assignment without Consent. Any purported assignment in contravention of Section 12.4(a) shall, at the option of the non-assigning Party, (i) be null and void and of no effect or (ii) terminate this Agreement. If the non-assigning Party elects to terminate this Agreement, the termination is effective as of the assignment's occurrence. Any termination is without prejudice to the non-assigning Party's claim for damages.

(c) Assignment with Consent. With respect to any assignment in compliance with Section 12.4, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and permitted assigns of the Parties.

12.5 Amendment; Approvals. Except as expressly provided herein, this Agreement may not be amended except by an instrument in writing referencing this Agreement and signed on behalf of both Parties. To be deemed effective pursuant to this Agreement, all approvals required hereunder shall be in writing.

12.6 Waivers. No term or provision of this Agreement shall be considered waived by either Party hereto, and no breach consented to by either Party hereto, unless such waiver or consent is in writing signed on behalf of the Party against whom the waiver or consent is asserted. No consent to or waiver of a breach by either Party hereto, whether express or implied, shall

constitute a consent to, waiver of, or excuse for any other, different or subsequent breach by such Party.

12.7 Construction. This Agreement is being entered into by and among competent and sophisticated parties who are experienced in business matters and represented by counsel and other advisors, and have been reviewed by the Parties and their counsel and advisors. Therefore, any ambiguous language in this Agreement will not be construed against any particular Party as the drafter of the language.

12.8 Notices.

(a) All notices and other communications hereunder shall be in writing and shall be sent to the respective Parties at the following addresses:

If to Cantex:

Cantex Pharmaceuticals, Inc.
1792 Bell Tower Lane, Weston, FL 33326
Attn: Stephen Marcus, President

with a copy to (which shall not constitute notice)

Greenberg Traurig LLP
3333 Piedmont Road, Suite 2500
Atlanta, GA 30305
Attn: Wayne H. Elowe, Esq.

and

If to SPL:

Scientific Protein Laboratories LLC
700 East Main Street
P.O. Box 158
Waunakee, WI 53597
Attn: President/CEO

with a copy to (but which shall not constitute notice):

Reinhart Boerner Van Deuren s.c.
1000 North Water Street
Milwaukee, WI 53202
Attn: Lawrence Burnett, Esq.

(b) All notices shall be deemed received: (i) if given by hand, immediately, (ii) if given by certified mail, three (3) business days after posting, (iii) if given by overnight courier service,

the next business day in the jurisdiction of the recipient, or (iv) if given by facsimile or electronic mail, upon confirmed receipt thereof by the recipient. Any Party may, by notice given in accordance with Section 12.8 of the Agreement to the other Party, designate another address or Person for receipt of notices hereunder.

12.9 Independent Contractor. In making and performing this Agreement, the Parties hereto are acting and shall act as independent contractors. Neither Party is, nor shall be deemed to be, an agent, legal representative, joint venturer or partner of the other Party for any purpose. Except as expressly permitted hereunder or with the prior written consent of the other Party, neither Party shall be entitled to (a) enter into any contracts in the name of or on behalf of the other Party, (b) pledge the credit of the other Party in any way or hold itself out as having authority to do so or (c) make commitments or incur any charges or expenses for or in the name of the other Party.

12.10 Severability. Wherever possible, each provision of this Agreement shall be interpreted in a manner as to be effective and valid under applicable Law. If, however, any provision of this Agreement, or portion thereof, is prohibited by Law or found invalid under any Law, only such provision or portion thereof shall be ineffective, without in any manner invalidating or affecting the remaining provisions of this Agreement or valid portions of such provision, which are hereby deemed severable.

12.11 Section Headings. All personal pronouns used in this Agreement, whether used in the masculine, feminine, or neuter gender, shall include all other genders, and the singular shall include the plural and vice versa. Titles of articles, sections and subsections are for convenience only and neither limit nor amplify the provisions of this Agreement. The use herein of the word "including," then following any general statement, term, or matter, shall not be construed to limit such statement, term, or matter to the specific items or matters set forth immediately following such word or to similar items or matters, whether or not non-limiting language (such words as "without limitation," or "but not limited to," or words of similar import) is used with reference thereto, but rather shall be deemed to refer to all other items or matters that could reasonably fall within the broadest possible scope of such general statement, term, or matter.

12.12 Supersession of Prior Agreements. This Agreement supersedes all prior agreements between the Parties. Upon execution of this Agreement, the Prior Agreement is hereby terminated and of no further force or effect.

12.13 Further Assurances. Each Party hereto agrees to do all acts and things and to make, execute and deliver such written instruments, as shall from time to time be reasonably required to carry out the terms and provisions of this Agreement.

12.14 Entire Agreement. Except where any other document (whether dated prior to or contemporaneously with this Agreement) expressly refers to this Agreement, this Agreement and the exhibits attached hereto constitute the entire understanding between the Parties with respect to the subject matter hereof and shall supersede any prior agreements, whether written or oral, arrangements or understandings, between the Parties relating to the subject matter hereof.

12.15 Counterparts. The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures delivered by facsimile or by e-mail in portable document format (PDF) shall be binding for all purposes hereof.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement effective as of the Effective Date.

CANTEX PHARMACEUTICALS , INC.	SCIENTIFIC PROTEIN LABORATORIES LLC
By: /s/ Stephen G. Marcus	By: /s/ Yan Wang
Name: Stephen G. Marcus	Yan Wang, PhD.
Title: President & CEO	President

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

EXHIBIT A

Specifications

Attached at the end of EXHIBIT B.

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

EXHIBIT B

Quality Agreement

[*]

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

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (**"Agreement"**), effective as of September 30, 2019 (the **"Effective Date"**), is made by and between **CHIMERIX, INC.**, a corporation organized and existing under the laws of the State of Delaware (**"Chimerix"**), and **SYMBIO PHARMACEUTICALS LIMITED**, a corporation organized and existing under the laws of Japan (**"SymBio"**).

RECITALS

WHEREAS, Chimerix owns or otherwise controls patents, patent applications, know-how and other information relating to the compound known as brincidofovir;

WHEREAS, SymBio is engaged in the discovery and development of antiviral therapies; and

WHEREAS, SymBio desires to obtain, and Chimerix is willing to grant to SymBio, a license under the Chimerix Technology to develop, make, have made, use, sell, have sold, offer for sale and import Compounds and Products in the Field, on the terms and subject to the conditions set forth herein.

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

ARTICLE 1

DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

1.1 "Acceptance for Filing" shall mean, with respect to an NDA filed for a Product: (a) in the United States, the receipt of written notice from the FDA in accordance with 21 C.F.R. §314.101(a)(2) (or its successor regulation) that such NDA is officially "filed"; (b) in an EU Market, the receipt of written notice of acceptance for filing of such NDA from the EMA or the applicable national Regulatory Authority in such EU Market (as applicable); or (c) in Japan, the receipt of written notice of acceptance for filing of such NDA from the PMDA.

1.2 "Accounting Standards" shall mean (a) U.S. generally accepted accounting principles, (b) Japan generally accepted accounting principles, or (c) international financial reporting standards; in any case, consistently applied throughout the organization of a Party (or a Related Party, as applicable).

1.3 "Acquirer Compound" shall mean:

(a) any Converting Compound that is Controlled by a Third-Party Acquirer of Chimerix, or any Affiliate of such Third-Party Acquirer, immediately prior to such Third-Party Acquirer's acquisition of Chimerix; or

(b) any Converting Compound that is Controlled by a Third-Party Acquirer of Chimerix, or any Affiliate of such Third-Party Acquirer, following such Third-Party Acquirer's acquisition of Chimerix, provided that such Converting Compound (i) was invented or reduced to practice without the use of any Chimerix Know-How (including any of Chimerix's confidential or proprietary information existing prior to such Third-Party's acquisition of Chimerix) and (ii) is not claimed by any of the Chimerix Patent Rights set forth in **Exhibit A**.

1.4 "Act" shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 *et seq*., or the Public Health Service Act, 42 U.S.C. §§262 *et seq*., as such may be amended from time to time.

1.5 "Actual Combination Product Net Sales" shall have the meaning provided in Section 1.50.

1.6 "Affiliate" shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of 50% or more of the voting securities of such Person, by contract or otherwise. For clarity, once a Person ceases to be an Affiliate of a Party then without any further action, such Person shall cease to have any rights under this Agreement by reason of being an Affiliate of such Party.

1.7 "Applicable Laws" shall mean the laws of any jurisdiction that are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions.

1.8 "Business Day" shall mean any day other than Saturday, Sunday, or a national holiday in Japan or the United States.

1.9 "Chimerix Field Patent Rights" shall mean Chimerix Patent Rights the claims of which are limited to methods of use in the Field and that do not claim methods of use of Compound or Product outside the Field.

1.10 "Chimerix Know-How" shall mean all Know-How Controlled by Chimerix or any of its Affiliates as of the Effective Date or during the Term.

1.11 "Chimerix NPP" shall have the meaning provided in Section 2.4.

1.12 "Chimerix Patent Rights" shall mean any and all Patent Rights Controlled by Chimerix or any of its Affiliates as of the Effective Date or during the Term that claim or otherwise Cover the composition of matter, manufacture or use of any Compound or Product (but excluding claims solely and specifically claiming the composition of matter, use, or manufacture of any Other Active); but specifically excluding Chimerix's (and its Affiliates') rights in Joint Patent Rights. The Chimerix Patent Rights shall include those listed in **Exhibit A**. Chimerix shall update **Exhibit A** from time-to-time, but no less than once per calendar year during the Term, to reflect the then-current list of Chimerix Patent Rights. Notwithstanding the foregoing, Chimerix Patent Rights shall not include any Patent Rights Controlled by any Third-Party Acquirer of Chimerix, or any Affiliate of such Third-Party Acquirer, except for any such Patent Rights claiming inventions made by such Third-Party Acquirer or its Affiliate after such Third-Party Acquirer's acquisition of Chimerix through (a) the use of Chimerix Know-How or (b) the practice of any invention that is then Covered by a Valid Claim of the Chimerix Patent Rights listed in Exhibit A.

1.13 "Chimerix Product" shall mean a Compound or Product developed, manufactured or commercialized by Chimerix, its Affiliates or licensees for the treatment or prevention of an Excluded Indication.

1.14 "Chimerix Technology" shall mean Chimerix Patent Rights and Chimerix Know-How.

1.15 "Combination Product" shall mean a pharmaceutical product comprising a fixed-dose formulation of Product or Compound and at least one Other Active.

1.16 "Commercially Reasonable Efforts" shall mean, (a) with respect to the efforts to be expended by a Party to accomplish any objective (other than any objective relating to development or commercialization of a Product, which is covered by clause (b) below), such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances, and (b) with respect to the efforts to be expended by a Party with respect to development or commercialization of a Product, the level of reasonable, diligent, good faith efforts that biopharmaceutical companies typically devote to the development, registration and commercialization of products owned by them that are at a similar stage in their development or product life and are of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval, the profitability of the product, and other relevant factors. "Commercially Reasonable Efforts" shall be determined on a country-by-country and Product-by-Product basis, and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" will change over time, reflecting changes in the status of a Product, as applicable, and the country or countries involved. It is expressly understood that the cessation of all development and commercialization efforts with respect to Product shall not constitute use of Commercially Reasonable Efforts. As used in this Section 1.16, "biopharmaceutical companies" shall mean companies in the biopharmaceutical industry of a size and stage of development similar to that of such Party, including those having human pharmaceutical product candidates or products in a similar stage of development to the Compound.

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

1.17 "Compound" shall mean:

(a) the 3-(Hexadecyloxy)propyl hydrogen ({[(2S)-1-(4-amino-2-oxo-1(2H)-pyrimidinyl)-3-hydroxy-2-propanyl]oxy}methyl)phosphonate (alternatively named Phosphonic acid, P-[[(S)-2-(4-amino-2-oxo-1(2H)-pyrimidinyl)-1-(hydroxymethyl)ethoxy]methyl]mono[3-(hexadecyloxy)propyl]ester), known as "brincidofovir";

(b) any Converting Compound that is Controlled by Chimerix as of the Effective Date;

(c) any Converting Compound that is Controlled by Chimerix after the Effective Date and during the Term; but excluding any Acquirer Compound;

(d) any metabolite of any of the compounds (excluding Acquirer Compounds) described in the preceding subparagraphs (a)-(c);

(e) any prodrug, conjugate or complex of any of the compounds (excluding Acquirer Compounds) described in the preceding subparagraphs (a)-(d); or

(f) any salt, free acid/base, solvate, enantiomer, isomer, hydrate, ester, racemate or polymorphic form of any of the compounds (excluding Acquirer Compounds) described in the preceding subparagraphs (a)-(e).

1.18 "**Compound INDs**" shall mean INDs # [*].

1.19 "**Committee**" shall mean the joint review committee established to facilitate the collaboration hereunder, as more fully described in Section 3.4.

1.20 "Confidential Information" shall mean any and all Information, whether communicated in writing or orally or by any other method, which is provided by or on behalf of one Party to the other Party in connection with this Agreement or pursuant to that certain Mutual Non-Disclosure Agreement between the Parties dated August 27, 2018.

1.21 "Control", **"Controls"** or **"Controlled by"** shall mean, with respect to any Patent Rights, Information, Know How, other intellectual property rights, or compounds, the possession by a Party or its Affiliates of the ability (whether by ownership, license or other right, *other than* pursuant to a license granted under this Agreement) to grant access to, or a license or sublicense of, such Patent Rights, Know-How, Information, other intellectual property rights, or compounds to the other Party as contemplated by this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

1.22 "Converting Compound" shall mean a pharmaceutically active compound that is converted *in vivo* into the active moiety cidofovir diphosphate. It is understood that brincidofovir is a Converting Compound.

1.23 "Cover" shall mean, with respect to a Patent Right and a Compound or Product, that, in the absence of a license under or ownership of such Patent Right, the manufacture, use, sale,

offer for sale or import of such Compound or Product would Infringe such Patent Right (or, in the case of a claim of a pending patent application, would, upon the issuance of a patent containing such claim, Infringe such claim). Cognates of the word "**Cover**" shall have correlative meanings.

1.24 "EMA" shall mean the European Medicines Agency or any successor entity thereto with jurisdiction over the European Union.

1.25 "Entity" shall mean any corporation, general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any limited liability company or joint stock company), firm or other enterprise, association, organization or entity.

1.26 "EU Market" shall mean any European Union member state, including the United Kingdom, whether or not a member of the European Union at any given time.

1.27 "Excluded Indication" shall mean the treatment or prevention of Smallpox.

1.28 "Export Control Laws" shall mean all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§1 *et seq*., the Arms Export Control Act, 22 U.S.C. §§2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.29 "FCPA" shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, *et seq*.) as amended.

1.30 "FDA" shall mean the U.S. Food and Drug Administration and any successor entity thereto.

1.31 "Field" shall mean the use of Compound or Product for the treatment or prevention of any and all Indications, but specifically *excluding* the use of Compound or Product for the treatment or prevention of any Excluded Indication.

1.32 "First Commercial Sale" shall mean, with respect to a given Product in a given country, the first commercial transfer or disposition for value of such Product by SymBio or a Related Party to a Third Party (other than a Related Party) for end use or consumption of such Product in such country after receipt of Marketing Approval for such Product in such country. For clarity, First Commercial Sale shall be determined on a Product-by-Product and country-by-country basis.

1.33 "Generic Version" shall mean, with respect to a Product, on a country-by-country basis, a pharmaceutical product that: (a) is sold in a given country by a Third Party, other than a Related Party or any other Person in a chain of distribution originating from SymBio or a Related Party; (b) contains the same Compound as such Product in the same dosage form as such Product; and (c) has been approved for marketing by the relevant Regulatory Authority in such country in

reliance on the Marketing Approval for such Product in such country, including any such pharmaceutical product that has been approved for marketing (i) in the United States, pursuant to Section 505(b)(2) or Section 505(j) of the Act (21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j), respectively), (ii) in the European Union or a European Union member state, as a "generic medicinal product" pursuant to Article 10 of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), (iii) in Japan, Article 14, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No 145 of 1960, as amended), or (iv) in any other country or jurisdiction, pursuant to any equivalent of the foregoing laws, regulations or directives, wherein the approval of such pharmaceutical product is based on reference to the Marketing Approval for such Product in such country and a demonstration of bio-equivalence to such Product and that may be substituted for the Product without any additional action by the physician or health care practitioner.

1.34 "GCP" shall mean the then current "good clinical practices" as such term is defined from time to time by the FDA, EMA, MHLW, or other Regulatory Authority of competent jurisdiction pursuant to its regulations, guidelines or otherwise, as applicable. Notwithstanding the foregoing, for purposes of the representations and warranties made by Chimerix in Section 7.2, "GCP" shall mean the then current "good clinical practices" as such term is defined from time to time by the FDA pursuant to its regulations, guidelines or otherwise.

1.35 "GLP" shall mean the then current "good laboratory practices" as such term is defined from time to time by the FDA, EMA, MHLW, or other Regulatory Authority of competent jurisdiction pursuant to its regulations, guidelines or otherwise, as applicable. Notwithstanding the foregoing, for purposes of the representations and warranties made by Chimerix in Section 7.2, "GLP" shall mean the then current "good laboratory practices" as such term is defined from time to time by the FDA pursuant to its regulations, guidelines or otherwise, as applicable.

1.36 "GMP" shall mean the then current "good manufacturing practices" as such term is defined from time to time by the FDA, EMA, MHLW, or other Regulatory Authority of competent jurisdiction pursuant to its regulations, guidelines or otherwise, as applicable. Notwithstanding the foregoing, for purposes of the representations and warranties made by Chimerix in Section 7.2, "GMP" shall mean the then current "good manufacturing practices" as such term is defined from time to time by the FDA pursuant to its regulations, guidelines or otherwise, as applicable.

1.37 "ICH" means the International Council for Harmonisation (formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.38 "IND" shall mean an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority, including any such application filed with the FDA pursuant to 21 CFR Part 312.

1.39 "Indication" shall mean a separate, and distinct class of disease, syndrome or medical condition in humans for which a separate NDA or a supplement (or other addition) to an existing NDA is required. For clarity, different stages of the same disease or condition shall not be different Indications, different lines of treatment of the same disease or condition shall not be different Indications, and the treatment or prevention of the same disease or condition in different populations (e.g., adult and pediatric) shall not be different Indications.

1.40 "Information" shall mean any and all proprietary data, information, materials and know-how (whether patentable or not) that are not in the public domain, including, (a) ideas, discoveries, inventions, improvements, technology or trade secrets, (b) pharmaceutical, chemical and biological materials, products, components or compositions, (c) methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies, (d) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data and information related thereto, (e) technical and non-technical data and other information related to the foregoing, and (f) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information or materials.

1.41 "**Infringe**" or "**Infringement**" means any infringement of a Patent Right as determined by Applicable Law, including direct infringement, contributory infringement or any inducement to infringe.

1.42 "Initiates" or **"Initiation"** shall mean, with respect to a human clinical trial, the administration of the first dose to the first patient/subject in such trial.

1.43 "Invention" shall mean any invention, whether or not patentable, made in the course and as a result of the conduct of the activities contemplated by this Agreement.

1.44 "Joint Invention" shall have the meaning provided in Section 8.1.

1.45 "Joint Patent Rights" shall have the meaning provided in Section 8.1.

1.46 "Know-How" shall mean any and all Information related to a Compound or Product, or any formulation, product improvement or Indication thereof, or necessary or useful for the development, manufacture, commercialization or use of any of the foregoing; but excluding, in each case, Information solely and specifically related to any Other Active.

1.47 "Marketing Approval" shall mean all approvals from the relevant Regulatory Authority in a given country necessary to market and sell a pharmaceutical product in such country, including pricing and reimbursement approvals if required for marketing or sale of such product in such country.

1.48 "**MHLW**" shall mean the Japanese Ministry of Health, Labor and Welfare, or any related or successor agency, or subagency thereto, including without limitation the Pharmaceuticals and Medical Devices Agency of Japan (the **"PMDA"**).

1.49 "NDA" shall mean: (a) in the United States, a New Drug Application (as more fully defined in 21 CFR 314.5, *et seq.*) filed with the FDA, or any successor application thereto; (b) in Japan, a New Drug Application as filed with the MHLW, or any successor application thereto; or (c) in any other country or group of countries, the equivalent application or submission for approval to market a pharmaceutical product filed with the governing Regulatory Authority in such country or group of countries.

1.50 "Net Sales" shall mean the gross amounts invoiced for sales or other dispositions of Products by or on behalf of SymBio or any of its Related Parties (each, a **"Selling Party"**) to Third Parties (other than Related Parties), less the following deductions actually incurred, allowed, paid or accrued by the Selling Party and specifically attributable to Products, all in compliance with applicable Accounting Standards, consistently applied by the Selling Party:

(a) normal and customary trade discounts, including trade, cash and quantity discounts or rebates credits or refunds, actually allowed or taken;

(b) credits or allowances actually granted or made for rejection of or return of previously sold Products, including recalls, or for retroactive price reductions and billing errors or for stocking allowances;

(c) governmental and other rebates (or credits or other equivalents thereof) actually granted to managed health care organizations, commercial insurance companies, pharmacy benefit managers (or equivalents thereof), distributors, national, state/provincial, local, and other governments, their agencies and purchasers, and reimbursers, or to trade customers, in each case with respect to Product;

(d) reasonable fees paid to wholesalers, distributors, selling agents (excluding sales representatives of the Selling Party), group purchasing organizations, Third-Party payors, other contractees and managed care entities, in each case with respect to the Product;

(e) charges separately invoiced for freight, insurance, transportation, postage and handling;

(f) taxes, custom duties or other governmental charges (including any tax such as a value added or similar tax or government charge but excluding what is commonly known as income tax) levied on or measured by the billing amount for Products, as adjusted for rebates and refunds; and

(g) the amount of any actual write-offs for bad debt on previously sold Product in accordance with the applicable Accounting Standards used by the Selling Party, consistently applied, not to exceed [*] in any calendar quarter; provided that any amount written off that is subsequently collected shall be treated as Net Sales in the calendar quarter in which it is collected;

provided that, in each case ((a) through (g)): (1) each such deduction is calculated in a manner consistent with the Selling Party's customary practice for pharmaceutical products and in accordance with applicable Accounting Standards, consistently applied by the Selling Party; (2) each such

deduction is directly allocable to Product, or apportioned on a good faith, fair and equitable basis to Product and other products of the Selling Party and its Affiliates such that Product does not bear a disproportionate portion of such deductions; and (3) in no event shall any particular amount identified above be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of deductions).

Sale or other disposition of Product by a Selling Party to another Selling Party for resale by such other Selling Party to a Third Party (other than a Selling Party) shall not be deemed a sale for purposes of this definition of Net Sales, *provided* that the subsequent resale to a Third Party (other than a Selling Party) is included in the computation of Net Sales. In the event of any sale or other disposition of Product for any consideration other than exclusively monetary consideration on *bona fide* arm's-length terms (including any sale or other disposition of Product by a Selling Party to another Selling Party for end use by such other Selling Party), or in the event Product is "bundled" for sale together with one or more other products for a single price in a country, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to have been sold exclusively for cash at the weighted (by sales volume) average sale price of such Product in *bona fide* arm's-length transactions (when sold alone, and not with other products) in the applicable country in which such sale or other disposition occurred during the applicable accounting period. Transfers or dispositions of Product for charitable, research and development, clinical or humanitarian purposes (in each case, without consideration), and Products provided at or below their manufacturing cost (determined in accordance with applicable Accounting Standards, consistently applied) and used in compassionate use or named patient programs, shall be disregarded in determining Net Sales.

On a country-by-country basis, if a Product is sold in a country as part of a Combination Product in a calendar quarter, Net Sales of such Product in such country during such calendar quarter for the purpose of determining royalties and commercialization milestone payments due hereunder shall be calculated as follows.

(i) In the event that both (x) a Single-Agent Product containing the Compound in such Combination Product is sold separately in finished form in such country during such calendar quarter and (y) the Other Active(s) in such Combination Product are sold separately in finished form in such country during such calendar quarter, then Net Sales of such Product shall be determined by multiplying the actual Net Sales of the Combination Product calculated pursuant to the preceding provisions of this Section 1.50 (**"Actual Combination Product Net Sales"**) in such country during such calendar quarter by the fraction, A / (A+B) where A is the weighted average sale price of such Single-Agent Product when sold separately in finished form in such country during such calendar quarter, and B is the weighted average sale price of the Other Active(s) in the Combination Product when sold separately in finished form in such country during such calendar quarter.

(ii) In the event that Single-Agent Product containing the Compound in such Combination Product is sold separately in finished form in such country during such calendar quarter, but the Other Active(s) in such Combination Product are not sold separately in finished form in such country during such calendar quarter, then Net Sales of such Product shall be calculated

by multiplying the Actual Combination Product Net Sales of the Combination Product in such country during such calendar quarter by the fraction A / C where A is the weighted average sale price of such Single-Agent Product when sold separately in finished form in such country during such calendar quarter and C is the weighted average sale price of the Combination Product in such country during such calendar quarter.

(iii) In the event that no Single-Agent Product containing the Compound in such Combination Product is sold separately in finished form in such country during such calendar quarter, but the Other Active(s) in such Combination Product are sold separately in finished form in such country during such calendar quarter, Net Sales of such Product shall be calculated by multiplying the Actual Combination Product Net Sales of the Combination Product by the fraction (C-B) / C, where B is the weighted average sale price of the Other Active(s) in the Combination Product when sold separately in finished form in such country during such calendar quarter, and C is the weighted average sale price of the Combination Product in such country during such calendar quarter.

(iv) In the event that neither a Single-Agent Product containing the Compound in such Combination Product is sold separately in finished form in such country during such calendar quarter, nor the Other Active(s) in such Combination Product are sold separately in finished form in such country during such calendar quarter, then the methodology for determining Net Sales of such Product in such country shall be mutually agreed in writing by the parties in good faith based on the relative contributions of the Compound and the Other Active(s) in such Combination Product to the total value of the Combination Product.

1.51 "Other Active" shall mean any active pharmaceutical ingredient that is not a Compound.

1.52 "Party" shall mean SymBio and Chimerix, individually, and **"Parties"** shall mean SymBio and Chimerix, collectively.

1.53 "Patent Rights" shall mean: (a) patents and patent applications (which for the purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention); (b) any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications; and (c) any and all foreign equivalents of the foregoing.

1.54 "Person" shall mean any natural person or Entity.

1.55 "Phase 3 Clinical Trial" shall mean a human clinical trial of a Product in any country designed to: (a) establish that such Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) support regulatory approval of such Product that would satisfy the requirements of 21 CFR 312.21(c) or its non-US equivalents.

1.56 "Pivotal Trial" shall mean: (a) a Phase 3 Clinical Trial; or (b) any other human clinical trial that the applicable Regulatory Authority has agreed, whether before Initiation of such trial (*e.g.*, pursuant to a special protocol assessment agreement with the FDA) or after Initiation of such trial (*e.g.*, based on an interim data analysis), is sufficient to form the primary basis of an efficacy claim in an NDA submission, regardless of whether the sponsor of such trial characterizes or refers to such trial as a "Phase 3," "Phase 2b" or "Phase 2b/3" trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context. If a human clinical trial does not constitute a Pivotal Trial at the time of Initiation of such trial, but is later determined by the applicable Regulatory Authority to be sufficient to form the primary basis of an efficacy claim in an NDA submission, then, for purposes of Section 4.2 hereof, and notwithstanding Section 1.42, "Initiation" of such Pivotal Trial shall be deemed to have occurred on the date of such determination by the applicable Regulatory Authority.

1.57 "PMDA" shall have the meaning set forth in Section 1.48.

1.58 "Product" shall mean any pharmaceutical composition or preparation in final form containing a Compound, in any formulation or dosage strength. For clarity, different formulations or dosage strengths of a given Product shall not be considered different Products for purposes of this Agreement, provided that nothing in this Section shall be interpreted to alter royalty payments or the calculation of the Royalty Term, as described in Article 4, or other references to "Product-by-Product" in this Agreement. For example, depending on the circumstances, one formulation of a given Product may, or may not, have a different Royalty Term in a country than another formulation of such Product in such country. By way of further example, if a Product in a particular formulation sold in a country is Covered by a Valid Claim of Chimerix Patent Rights, and a Product in a different formulation sold in that country is not Covered by such Valid Claim, the Royalty Term for the first Product in such country may be longer than the Royalty Term for the other Product in such country.

1.59 "Product Filings" shall have the meaning provided in Section 1.61.

1.60 "Regulatory Authority" shall mean any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction.

1.61 "Regulatory Documentation" shall mean all regulatory applications, filings, submissions, registrations, licenses, authorizations and approvals, including all INDs, NDAs and Marketing Approvals (collectively, **"Product Filings"**); all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority); and all reports and documentation in connection with clinical studies and tests (including study reports and study protocols, and copies of all interim study analysis), and all data contained in any of the foregoing, including all INDs, NDAs, advertising and promotion documents, manufacturing data, drug master files, clinical data, adverse event files and complaint files, in each case related to a Compound or Product.

1.62 "Regulatory Exclusivity" shall mean exclusive marketing rights or data exclusivity rights conferred by the applicable Regulatory Authority in a country or jurisdiction on the holder

of a Marketing Approval for a pharmaceutical product in such country or jurisdiction, including, by way of example and not of limitation, regulatory data exclusivity, orphan drug exclusivity, new chemical entity exclusivity and pediatric exclusivity.

1.63 "Related Party" shall mean each of SymBio's Affiliates and its and their respective Sublicensees hereunder.

1.64 "Royalty Term" shall have the meaning provided in Section 4.5.

1.65 "Single-Agent Product" shall mean a Product containing Compound as its sole active pharmaceutical ingredient.

1.66 "Smallpox" shall mean any orthopox virus, including variola virus.

1.67 "Sublicensee" shall mean a Third-Party sublicensee under the license granted by Chimerix to SymBio pursuant to Section 2.1, whether such Third Party's sublicense was granted to it directly by SymBio or its Affiliate or indirectly through one or more tiers of sublicense. As used in this Agreement, "Sublicensee" shall not include: (a) a Third Party distributor of Product that has no royalty or other payment obligations to SymBio or any of its Affiliates that are calculated based on amounts invoiced or received by such Third Party for sales of Product; (b) a Third Party distributor of Product that (i) does not take title to Product, (ii) does not invoice Product sales to Third Party customers and (iii) is responsible only for inventory management and distribution with respect to Product on behalf of SymBio or its Affiliate; or (c) a Third Party to which SymBio or its Affiliates has granted the right solely to market or promote, but not to sell or offer for sale, Product in the Field.

1.68 "SymBio Know-How" shall mean all Know-How that: (a) is generated, developed or obtained by or on behalf of SymBio or any of its Affiliates or Sublicensees during the Term in the course of conducting research, development, manufacturing, regulatory or commercialization activities with respect to Compound or Product; or (b) is otherwise Controlled by SymBio or any of its Affiliates during the Term and is necessary for, or is actually used in, the conduct of development, manufacture, use or commercialization activities with respect to Compound or Product.

1.69 "SymBio Patent Rights" shall mean: (a) all Patent Rights claiming or Covering Inventions made by or on behalf of SymBio or any of its Affiliates or Sublicensees during the Term in the course of conducting research, development, manufacturing, regulatory or commercialization activities with respect to Compound or Product; and (b) all other Patent Rights Controlled by SymBio or any of its Affiliates that claim inventions that are necessary for, or is actually used in, the conduct of development, manufacture, use or commercialization activities with respect to Compound or Product; but specifically excluding SymBio's (and its Affiliates') rights in Joint Patent Rights.

1.70 "SymBio Technology" shall mean SymBio Patent Rights and SymBio Know-How.

1.71 "Term" shall have the meaning provided in Section 9.1.

1.72 "**Territory**" shall mean the entire world.

1.73 **"Third Party"** shall mean an Entity other than SymBio and its Affiliates, and Chimerix and its Affiliates.

1.74 **"Third-Party Acquirer"** shall have the meaning provided in Section 12.5(a).

1.75 **"Upfront Payment"** shall have the meaning provided in Section 4.1.

1.76 **"Valid Claim"** shall mean: (a) a claim of an issued and unexpired patent, or a supplementary protection certificate thereof, which has not been held permanently revoked, unenforceable or invalid by a decision of a court, patent office or other forum of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of a pending patent application that has not been abandoned, finally rejected or expired without the possibility of appeal or re-filing and that has not been pending for more than seven (7) years from the filing date of the earliest patent application from which such claim derives priority.

ARTICLE 2

LICENSE GRANT

2.1 **License Grant.** Subject to the terms and conditions of this Agreement, Chimerix hereby grants to SymBio an exclusive (even as to Chimerix and its Affiliates), royalty-bearing license including the right to sublicense through multiple tiers, under the Chimerix Technology and Chimerix's interest in the Joint Patent Rights; in each case, solely to discover, develop, make, have made, use, sell, have sold, offer for sale, market, export, import or otherwise commercialize Compounds and Products in the Field in the Territory during the Term.

2.2 **Sublicensing.** Any sublicense granted by SymBio under this Agreement (directly or indirectly through its Affiliate) to a Third Party shall be: (a) in writing; and (b) subject and subordinate in all respects to, and consistent with, the terms and conditions of this Agreement. SymBio shall provide Chimerix with a copy of any sublicense agreement entered into by SymBio or its Affiliate, and any amendment thereto, within 30 days of its execution; provided that any such copy may be redacted to exclude any information not reasonably necessary to confirm compliance with the terms hereof. SymBio shall be liable for the failure of its Sublicensees to comply with the relevant obligations under this Agreement and shall, at its own cost, enforce compliance by Sublicensees with the terms of the sublicense agreements. Chimerix shall provide reasonable cooperation with SymBio's efforts to enforce compliance by Sublicensees through litigation or arbitration when necessary, by providing documents within its control and making witnesses available to the extent reasonable and practicable, at the request of SymBio. SymBio will reimburse Chimerix for actual expenses incurred in connection with such cooperation.

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

2.3 Technology Transfer.

(a) Inventory. By a date mutually agreed between the Parties, not to exceed 120 days after the Effective Date, but subject to Chimerix's receipt of the Upfront Payment, Chimerix shall transfer to SymBio at no additional cost to SymBio, inventory of Compound as set forth on **Exhibit B** (collectively, **"Inventory"**).

(b) Manufacturing Technology Transfer. Within 20 Business Days after the Effective Date, subject to Chimerix's receipt of the Upfront Payment, Chimerix shall transfer or cause to be transferred (including from its Third-Party contract manufacturers) to SymBio, or an Affiliate or Third-Party manufacturer designated by SymBio, copies of all Chimerix Know-How related to the manufacture of Compound or Product in Chimerix's Control (whether in the possession of Chimerix, its Affiliate or a Third-Party contract manufacturer), in order to enable SymBio (or its designee) to manufacture Compound or Product for use in the Field using the process employed by or on behalf of Chimerix to manufacture Compound or Product in accordance with the plan set forth on **Exhibit C**. In addition, Chimerix shall provide SymBio with an introduction to Chimerix's Third-Party contract manufacturer(s) for Compound and Product and shall deliver to such contract manufacturer(s) written authorization to: (i) contract with SymBio for the manufacture and supply of Compound and Product; (ii) manufacture Compound and Product on behalf of SymBio; and (iii) disclose to SymBio such Chimerix Know-How regarding manufacture of Compound and Product in the possession of such contract manufacturer as is necessary or useful for SymBio to manufacture or have manufactured Compound and Product for use in the Field. Chimerix shall use Commercially Reasonable Efforts to provide support to SymBio or its Affiliate (as may be designated by SymBio) in obtaining the services of a Third-Party contract manufacturer.

(c) Chimerix Know-How. Within 20 Business Days after the Effective Date, subject to Chimerix's receipt of the Upfront Payment, Chimerix shall transfer to SymBio all clinical safety, toxicology and other information (including Information) within the Chimerix Know-How related to the Compound or Product that is available in written, graphic, electronic or other tangible form (or true and complete copies thereof), and to the extent such data exists in electronic form, Chimerix may provide the same to SymBio in electronic form. If Chimerix generates any material new clinical safety, toxicology and other information (including Information) within the Chimerix Know-How related to the Compound or Product that is available in written, graphic, electronic or other tangible form, Chimerix shall promptly (at the latest within 45 days from when the information is generated) transfer true and complete copies thereof to SymBio, and to the extent such data exists in electronic form, Chimerix may provide the same to SymBio in electronic form.

(d) Scientific Information. Within 20 Business Days after the Effective Date, subject to Chimerix's receipt of the Upfront Payment, Chimerix shall disclose to SymBio all existing data and information generated in any preclinical or clinical study of Compound or Product in the Field conducted by or on behalf of Chimerix, including a copy of the final study report from each such study, and provide to SymBio copies of all Regulatory Documentation for Compound and Product in the Field in Chimerix's possession.

Subject to the terms and conditions of this Agreement, Chimerix grants SymBio the right to access and reference all Product Filings for Product in the Territory that are held by Chimerix

as of the Effective Date or during the Term, solely for the purpose of obtaining and maintaining regulatory approvals for Product in the Field in the Territory; and SymBio grants Chimerix the right to access and reference all Product Filings for Product in the Territory that are held by SymBio or any of its Affiliates or Sublicensees during the Term, solely for the purpose of obtaining and maintaining regulatory approvals for Product outside the Field in the Territory. Any translation costs associated with any access and reference of future regulatory filings and correspondences with Regulatory Authorities under this Agreement shall be borne by the Party seeking the right to access and reference the applicable filing. Each Party shall, promptly upon request of the other Party, file with applicable Regulatory Authorities such letters of authorization, access or cross-reference as may be necessary to accomplish the intent of this Section 2.3(d).

(e) PV Agreement. Prior to initiation by SymBio of any clinical trial of Product, the Parties shall negotiate in good faith and enter into a pharmacovigilance/safety data exchange agreement for Products (the **"PV Agreement"**), which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions or experiences sufficient to permit each Party to comply with its regulatory and other legal obligations within the applicable timeframes. The PV Agreement's terms and conditions shall be no less stringent than U.S., Japan and ICH guidelines, such that each Party shall be able to comply with all regulatory and legal requirements regarding the management of safety data by providing for the exchange of relevant information in appropriate format within applicable timeframes. Subject to the foregoing, each Party shall be responsible for monitoring all clinical experiences with respect to Product in the course of its own Product development activities and filing all required reports with respect thereto in its respective field (*i.e.*, with respect to SymBio, in the Field, and with respect to Chimerix, in the Excluded Indication).

(f) Technical Assistance. For a period of [*], beginning on the Effective Date (the **"Technical Assistance Period"**), at SymBio's request and upon reasonable advance notice to Chimerix, Chimerix shall provide reasonable technical assistance to SymBio in the practice of the Chimerix Know-How transferred to SymBio pursuant to this Section 2.3 (**"Technical Assistance"**). For clarity, Technical Assistance excludes, and Chimerix will not be responsible for, the performance of any additional research, development or manufacturing (including CMC) work, as well as the meetings of the Joint Review Committee in Section 3.4. Technical Assistance shall be provided by Chimerix as follows: [*] SymBio shall reimburse Chimerix for Technical Assistance at the following hourly rates:

[*] hours	$[*]
[*] hours	$[*]
[*] hours	$[*]

Chimerix shall use Commercially Reasonable Efforts to provide the Technical Assistance in a timely manner consistent with the timelines set forth in **Exhibit C** hereto. In no event shall Chimerix be obligated to provide more than an aggregate of [*] of Technical Assistance pursuant to this

Section 2.3(f) during the Technical Assistance Period, or to provide any Technical Assistance after the Technical Assistance Period. For clarity, SymBio may contract with Chimerix's contract manufacturer of Compound or Product for technical assistance at SymBio's sole expense, which will not be considered Technical Assistance under this Section 2.3(f).

(g) Regulatory Support. Without limiting Chimerix's obligations set forth elsewhere in this Section 2.3, at SymBio's reasonable request, Chimerix shall provide reasonable cooperation, and reasonable support in the form of reasonable consultation to SymBio, in connection with SymBio's preparing and submitting Regulatory Documentation to applicable Regulatory Authorities, including [*]. For clarity, SymBio shall be solely responsible for preparing and submitting Product Filings for Product in the Field in the Territory.

(h) No Transfer of Compound INDs. For clarity, in no event shall Chimerix have any obligation to transfer or assign to SymBio any Compound INDs.

2.4 Reserved Rights. Chimerix hereby expressly reserves the exclusive right to practice, and to grant licenses under, the Chimerix Technology for any and all purposes other than the specific purposes for which the Chimerix Technology is exclusively licensed to SymBio under Section 2.1. Without limiting the generality of the foregoing, Chimerix hereby expressly reserves the exclusive, worldwide right to practice, and to grant licenses under, the Chimerix Technology to discover, develop, make, have made, use, sell, have sold, offer for sale, market, import, export and otherwise commercialize (a) Chimerix Products, (b) Compound or Product outside the Field, or (c) any compound that is not a Compound or product that is not a Product for any and all uses. In addition to the foregoing, and notwithstanding the exclusivity of the license granted in Section 2.1, Chimerix shall have the right to continue its existing named patient program for Product (the **"Chimerix NPP"**) until such time as Chimerix's existing supply of Product for such purpose is exhausted. SymBio shall have no responsibility for the Chimerix NPP.

2.5 Negative Covenants.

(a) By SymBio. SymBio hereby covenants not to practice, and not to permit or cause any Related Party or other Third Party to practice, any Chimerix Technology for any purpose other than as expressly authorized in this Agreement. Without limiting the generality of the foregoing, SymBio shall not, directly or indirectly:

(i) develop, use, make, have made, sell, have sold, offer for sale, export, import or otherwise commercialize any Compound or Product outside the Field, including any Chimerix Product in any Excluded Indication; or

(ii) permit or cause any of its Related Parties or any Third Party to engage in any of the activities described in the preceding clause (i).

(b) By Chimerix. Chimerix hereby covenants not to practice, and not to permit or cause any Affiliate, licensee or other Third Party to practice, any SymBio Technology for any purpose other than as expressly authorized in this Agreement. Without limiting the generality of the foregoing, Chimerix shall not, directly or indirectly:

(i) practice any SymBio Patent Rights for any purpose other than as expressly authorized in Section 2.6; or

(ii) develop, use, make have made, sell, have sold, offer for sale**,** export, import or otherwise commercialize any Compound or Product (including Chimerix Product) in the Field.

2.6 License Grant-Back to Chimerix. Subject to the terms and conditions of this Agreement, SymBio hereby grants to Chimerix a limited, exclusive, royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense through multiple tiers, under SymBio Technology and SymBio's interest in the Joint Patent Rights, solely to develop, make, have made, use, sell, have sold, offer for sale, export, import and otherwise commercialize Chimerix Products outside the Field in the Territory. Chimerix shall, during the Term, provide SymBio access to Chimerix Controlled Information that is directly related to the use of any SymBio Technology or SymBio's interest in the Joint Patent Rights licensed to Chimerix pursuant to this Section 2.6. Prior to, and as a condition of, Chimerix granting to any Third Party a sublicense under the license granted to Chimerix pursuant to this Section 2.6, Chimerix shall procure from such Third Party licensee the right to share, and shall share with SymBio, any subsequent Information generated by such Third Party sublicensee related to the Product. For the avoidance of doubt, Chimerix is not obligated to share with SymBio any Information generated by any Third Party licensee that is a government entity.

2.7 No Implied Licenses. No right or license under any Patent Rights, Know-How or other Information is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. For the avoidance of doubt, Chimerix does not grant to SymBio any license or other right with respect to any active pharmaceutical ingredient that is not a Compound. SymBio does not grant to Chimerix any license or other right with respect to any other SymBio intellectual property except as described in Section 2.6 and, if applicable, Section 9.5(b).

ARTICLE 3

DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

3.1 Responsibility. SymBio (itself or with or through its Related Parties or subcontractors) shall be solely responsible, at its own expense, for, and shall control all aspects of, worldwide development (including pre-clinical and clinical development), manufacture, registration and commercialization (including marketing, promoting, selling, distributing and determining pricing for) Compounds and Products in the Field in the Territory. Without limiting the generality of the foregoing, SymBio (itself or with or through its Related Parties or subcontractors) shall be solely responsible for preparing and submitting all required regulatory filings in connection with obtaining and maintaining Marketing Approvals with respect to Compounds and Products in the Field in the Territory, including all INDs and NDAs, at SymBio's sole expense. All of such submissions and other regulatory filings relating to any Compound or Product in the Field shall be submitted in the name of, and owned by, SymBio (or a Related Party, as applicable). For clarity, SymBio shall have no responsibility for: (a) any research, development,

manufacture, use or commercialization of Compound or Product conducted by or on behalf of Chimerix prior to the Effective Date; or (b) the conduct of the Chimerix NPP either before or after the Effective Date.

3.2 Diligence. SymBio (itself or with or through its Related Parties or subcontractors) shall use Commercially Reasonable Efforts to develop and obtain Marketing Approval for at least one Product in the Field in Japan, the United States and the EU Market. Without limiting the generality of the foregoing, SymBio (itself or with or through its Related Parties or subcontractors) shall use Commercially Reasonable Efforts to perform SymBio's development plan for the Product in the Field, as such development plan may be amended by SymBio from time to time in its sole discretion (the **"Development Plan"**). The initial Development Plan is attached hereto as **Exhibit D**. SymBio (itself or with or through its Related Parties or subcontractors) shall use Commercially Reasonable Efforts to promote, market, distribute, sell, have sold and otherwise commercialize at least one Product in the Field in each of Japan, the United States and the EU Market, in each case, after Marketing Approval is obtained in such territory. Should Chimerix decide to abandon any Marketing Approval for the Excluded Indication for any reason, Chimerix shall: (1) provide reasonably prompt notice to SymBio; and (2) discuss with SymBio via teleconference or in person for a period of at least 30 days (or such period as the parties otherwise mutually agree) after giving SymBio such notice and consider SymBio's position in good faith in determining whether to abandon the relevant Marketing Approval.

3.3 Records. SymBio shall maintain, or cause to be maintained, complete and accurate records of all development work conducted by or on behalf of SymBio with respect to Compound or Product in the Field, including all results, data, inventions and developments made in the performance of such development work. Chimerix shall maintain, or cause to be maintained, complete and accurate records of all development work conducted by or on behalf of Chimerix with respect to Compound or any Chimerix Product outside of the Field, including all results, data, inventions and developments made in the performance of such development work. All such records maintained by either Party pursuant to this Section 3.3 shall be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each Party shall maintain records under this Section 3.3 regardless of whether they have been provided to the other Party. Records maintained under this Section 3.3 shall be maintained for at least the minimum required period under applicable law.

3.4 Joint Review Committee

(a) Composition of the Joint Review Committee. The Parties hereby establish a joint review committee (the **"Committee"** or the **"JRC"**) to review, consider, and discuss the development, manufacture, and commercialization of the Product in the Field in the Territory. The Committee shall be comprised of three (3) representatives of Chimerix and three (3) representatives of SymBio. Each Party shall provide the other with a list of its initial members of the Committee no later than thirty (30) days after the Effective Date, and each Party may change its representatives on the Committee from time to time, in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and familiarity with respect to development, manufacture and commercialization of

pharmaceutical compounds. Additional non-employee representatives or consultants of a Party may from time to time, by mutual consent of the Parties, be invited to attend Committee meetings, subject to such representative's or consultant's written agreement to comply with the requirements of Section 6.1. The Committee shall be chaired by a representative of SymBio, who shall prepare written draft minutes of all Committee meetings within thirty (30) days following such meetings, and shall circulate such minutes to the Committee members. Chimerix shall provide comments, if any, within thirty (30) days from circulation of the draft minutes. SymBio shall issue final minutes within thirty (30) days following receipt of Chimerix's written comments, if any. Decisions of the Committee shall be made by unanimous vote, with each Party's representatives collectively having a single vote. In the event that the Committee cannot or does not, after good faith efforts for a period of thirty (30) days, reach agreement on an issue, the issue will be escalated and communicated to the appropriate CEO of SymBio and the Chief Executive Officer of Chimerix (together, the **"Executives"**), who shall endeavor to facilitate a resolution of such issue. If the Executives have not resolved such issue within ten (10) Business Days following the communication of the issue to them, then the resolution and/or course of conduct shall be determined by SymBio, in its sole discretion (and such matter shall not be subject to dispute resolution pursuant to Section 11.2), subject to Section 3.4(c). Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.

(b) Meetings and Responsibilities. The Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than twice annually, with the location for such meetings to be determined by agreement between the Parties. Alternatively, the Committee may meet by means of teleconference, videoconference or other similar communications equipment. The Committee shall be responsible for:

(i) reviewing development and regulatory strategy for Product in the Field in the Territory;

(ii) reviewing amendments to the Development Plan;

(iii) facilitating the exchange of Product-related data and information between the Parties;

(iv) serving as the principal means for SymBio to keep Chimerix reasonably informed regarding SymBio's development, manufacturing, registration and commercialization plans, efforts and results with respect to Product in the Territory; and

(v) serving as the principal means for Chimerix to keep SymBio reasonably informed regarding development and regulatory progress with respect to formulations of Compound for the Excluded Indication relevant to development and regulatory process in the Field (subject to any Chimerix confidentiality restrictions).

(c) Limitation on JRC Authority. Notwithstanding the establishment and existence of the JRC, each Party shall retain the rights, powers and discretion granted to it hereunder, and the JRC shall not be delegated or vested with rights, powers or discretion unless such delegation

or vesting is expressly provided herein. In addition, and notwithstanding any other provision of this Agreement to the contrary, the JRC shall have no right or authority:

(i) to interpret, modify, amend, or waive compliance with any provision of, or any right or remedy under, this Agreement;

(ii) to determine whether or not a Party has complied with any of its obligations under this Agreement;

(iii) to determine whether or not, or when, any milestone event set forth in Section 4.2 or Section 4.3 has been achieved;

(iv) to determine any issue in a manner that would conflict with the express terms of this Agreement; or

(v) to make any decision or approve any matter that is expressly stated to require the mutual written agreement of the Parties or the written consent of one or both Parties.

3.5 Compliance with Applicable Laws. SymBio shall conduct, and shall cause its Related Parties to conduct, all development, regulatory, manufacturing, promotion, marketing, distribution, sale and pharmacovigilance activities with respect to Compounds and Products anywhere in the world in compliance with all Applicable Laws and, as applicable, GLP, GCP or GMP.

ARTICLE 4

PAYMENTS

4.1 Upfront Payment. In partial consideration for the rights and licenses granted to SymBio hereunder, SymBio shall pay to Chimerix, no later than fifteen (15) Business Days after the Effective Date, an upfront payment in the amount of $5 million USD (the **"Upfront Payment"**). SymBio's failure to pay the Upfront Payment within fifteen (15) Business Days of the Effective Date shall render this Agreement null and void *ab initio*.

4.2 Development and Regulatory Milestone Payments. Within 45 days of the first achievement of each of the milestone events set forth in the table below by SymBio or any Related Party, SymBio shall provide Chimerix with written notice of such achievement and shall pay to Chimerix the corresponding one-time, non-refundable, non-creditable milestone payment set forth below:

Milestone Event by Country/Region	Milestone Payment (USD)
(Japan)	
[*]	$[*] million
[*]	$[*] million
[*]	$[*] million
(US/EU)	
[*]	$[*] million
[*]	$[*] million
[*]	$[*] million

Each of the above milestone payments shall only be paid once, for the first achievement of the corresponding milestone event by any Product (regardless of the number of times such milestone event is achieved by a Product, the number of Indications for which such milestone event is achieved by a Product, or the number of Products that achieve such milestone event, and regardless of whether any such milestone event is achieved by the same Product that achieved any other milestone event or by a different Product).

4.3 Commercialization Milestone Payments. Within [*] days following the end of the first calendar year in which each of the events set forth below is achieved, SymBio shall pay to Chimerix the corresponding one-time, non-refundable, non-creditable milestone payment set forth below:

Commercialization Milestone Event (USD)	Commercialization Milestone Payment (USD)
First calendar year in which aggregate annual Net Sales of all Products in the Territory exceed $[*]	$[*] million
First calendar year in which aggregate annual Net Sales of all Products in the Territory exceed $[*]	$[*] million
First calendar year in which aggregate annual Net Sales of all Products in the Territory exceed $[*]	$[*] million
First calendar year in which aggregate annual Net Sales of all Products in the Territory exceed $[*]	$[*] million

Each of the foregoing commercial milestone payments shall be paid only once, for the first calendar year in which the corresponding commercial milestone event is achieved. If multiple commercial milestone events are achieved in any given calendar year, the commercial milestone payments corresponding to all of such achieved commercial milestone events shall be paid within [*] days of the end of such calendar year.

4.4 Royalties. Subject to Sections 4.5, 4.6, 4.7 and 4.8 below, SymBio shall pay Chimerix a royalty equal to [*]% of Net Sales of all Products in the Territory by SymBio and Related Parties.

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

4.5 Royalty Term. Royalties under Section 4.4 shall be payable on a Product-by-Product, country-by-country basis during the period of time commencing on the First Commercial Sale of a Product in a country and ending upon the latest of: (a) 10 years from the date of First Commercial Sale of such Product in such country; (b) expiration of Regulatory Exclusivity for such Product in such country; and (c) expiration of the last-to-expire Valid Claim of the Chimerix Patent Rights Covering the manufacture, use or sale of such Product in such country (the **"Royalty Term"**). On a Product-by-Product and country-by-country basis, upon expiration of the Royalty Term for a Product in a country, SymBio's license under Section 2.1 with respect to such Product in such country shall become fully paid-up, irrevocable and perpetual. Notwithstanding the foregoing, for sales of a Product in a country that occur (x) after 10 years from the date of First Commercial Sale of such Product in such country and (y) after either (i) expiration of the last-to-expire Valid Claim of the Chimerix Patent Rights Covering the manufacture, use or sale of such Product, or (ii) a Generic Version of such Product is on the market with a market share of more than [*]% and less than [*]% (as calculated in Section 4.8), in each case ((i) and (ii)) in such country where (z) a Regulatory Exclusivity of the Product exists in such country, SymBio shall pay to Chimerix a royalty equal to [*]% of Net Sales of the Product in the Indication that are covered by the Regulatory Exclusivity in such country with no adjustment for generic competition, and no royalty shall be due for sales of Product in an Indication not covered by the Regulatory Exclusivity in such country.

4.6 Third-Party Licenses. In the event that SymBio determines that it is necessary to obtain one or more licenses under issued and unexpired Patent Rights of Third Parties in order to make, have made, use, offer to sell, sell or import Product in a country (**"Third-Party Patent Licenses"**), [*]% of the royalties actually paid to Third Parties under such Third-Party Patent Licenses by SymBio for the sale of such Product in such country for a calendar quarter shall be creditable against the royalty payments due Chimerix by SymBio with respect to Net Sales of such Product in such country for such calendar quarter; *provided, however,* that in no event shall the royalties otherwise owed by SymBio to Chimerix for such calendar quarter in such country be reduced by more than [*]% as a result of any and all such offsets under this Section 4.6 in the aggregate. Any portion of the royalties paid to Third Parties under such Third-Party Patent Licenses with respect to such Product in such country that SymBio would, but for the foregoing limitation on royalty reductions, be entitled to deduct under this Section 4.6 shall be carried over and applied against royalties payable to Chimerix in respect of such Product in such country in subsequent calendar quarters until the full deduction is taken; *provided, however,* that in no event shall the royalties otherwise owed by SymBio to Chimerix for any calendar quarter in such country be reduced by more than [*]% as a result of any and all such offsets under this Section 4.6 in the aggregate. For clarity, in no event shall SymBio be entitled to deduct from royalties payable to Chimerix hereunder any royalties or other amounts that may be paid or payable by SymBio to any Third Party with respect to Patent Rights or other intellectual property rights Covering any Other Active in a Product that is a fixed-dose combination of Compound and one or more Other Actives.

4.7 Compulsory Licenses. If a compulsory license is granted to a Third Party with respect to Product in any country with a royalty rate lower than the royalty rate under Section 4.4, then the royalty rate applicable to Net Sales of such Product in that country under Section 4.4 shall be reduced to a rate that is [*] ([*]%) percentage points (*i.e.*, [*] basis points) less than the rate paid by the compulsory licensee; *provided, however,* that if the royalty rate payable by the compulsory

licensee with respect to Net Sales of such Product in such country is [*]% or less, then SymBio shall pay to Chimerix [*]% of the royalties received by SymBio or its Affiliate with respect to Net Sales of such Product in such country by such compulsory licensee.

4.8 Adjustment for Generic Competition. Subject to the exception set forth in Section 8.4(a)(ii), on a Product-by-Product and country-by-country basis, during any portion of the Royalty Term for a Product in a country if one or more Generic Versions of such Product account for [*]% or more of aggregate unit sales of such Product and such Generic Version(s) in such country in a calendar quarter, as determined by reference to applicable sales data obtained from IQVIA or from such other source for such sales data as may be agreed upon by the Parties (provided that such other source, if any, shall be generally recognized as a reliable source for pharmaceutical sales data among major pharmaceutical companies), then for the remainder of the Royalty Term for such Product in such country, the royalties payable by SymBio under Section 4.4 with respect to Net Sales of such Product in such country shall be reduced by [*]%.

ARTICLE 5

PAYMENT; RECORDS; AUDITS

5.1 Payment; Reports. Royalties under Section 4.4 shall be calculated and reported for each calendar quarter during the Royalty Term and shall be paid within [*] days after the end of the calendar quarter. Each payment of royalties shall be accompanied by a report of Net Sales of Products by SymBio and Related Parties in sufficient detail to permit confirmation of the accuracy of the payment made, including gross sales and Net Sales of Products on a Product-by-Product and country-by-country basis, the deductions from gross sales (by major category as set forth in the definition of Net Sales), details of any royalty credits taken pursuant to Section 4.6 on a Third-Party Patent License-by-Third-Party Patent License basis, any applicable reductions or adjustments made pursuant to Section 4.7 or Section 4.8, the royalty payable, and the exchange rates used.

5.2 Exchange Rate; Manner and Place of Payment. All payment amounts in this Agreement are expressed in U.S. dollars, and all payments hereunder shall be payable in U.S. dollars. When conversion of payments from any foreign currency is required, such conversion shall be calculated using an exchange rate equal to the average of the interbank rates of exchange for such currency as reported at OANDA.com during the calendar quarter for which payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to the bank and account designated in writing by Chimerix.

5.3 Income Tax Withholding. Chimerix shall pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by SymBio from any payment made to Chimerix under this Agreement, SymBio shall (a) deduct such taxes from the payment made to Chimerix, (b) timely pay the taxes to the proper taxing authority, (c) send proof of payment to Chimerix and certify its receipt by the taxing authority within 60 days following such payment, and (d) cooperate with Chimerix in any way reasonably requested by Chimerix, to obtain available reductions, credits or refunds of such taxes. Without limiting the generality of the foregoing, upon request by Chimerix, SymBio shall provide Chimerix such information in SymBio’s possession as may be reasonably necessary for Chimerix to obtain the

benefit of any present or future treaty against double taxation that may apply to payments made to Chimerix under this Agreement.

If SymBio is required to make a payment to Chimerix subject to a deduction or withholding of taxes, and if such deduction or withholding of tax obligation arises solely as a result of the assignment of this Agreement by SymBio or as a result of any failure on the part of SymBio to comply with Applicable Laws relating to the withholding of taxes, in each case, after the Effective Date, that has the effect of increasing the deduction or withholding of taxes on such payment above the amounts of deduction or withholding of taxes that would otherwise be deducted or withheld prior to such assignment of this Agreement or prior to such failure by SymBio to comply with such Applicable Laws, as applicable (a **"SymBio Withholding Tax Action"**), then the payment by SymBio (in respect of which such deduction or withholding of taxes is required to be made) shall be increased by the amount of such additional deduction or withholding taxes (the **"Additional Tax"**), but solely to the extent that (i) such Additional Tax arises solely as a direct result of such SymBio Withholding Tax Action and (ii) such Additional Tax cannot be recovered by Chimerix. The Additional Tax, along with any other taxes deducted and withheld from the payment made by SymBio, shall be timely remitted to the proper governmental authority for the account of Chimerix in accordance with Applicable Laws.

5.4 Audits. SymBio shall keep (and shall cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of Products in sufficient detail to permit Chimerix to confirm the accuracy of all royalty payments due hereunder for at least three (3) full calendar years following the end of the calendar year to which they pertain. Chimerix shall have the right, once annually, to cause an independent, certified public accountant reasonably acceptable to SymBio to audit such records solely to confirm Net Sales and royalties for a period covering not more than the preceding three (3) full calendar years. No calendar year shall be subject to audit under this Section 5.4 more than once. Such audits may be exercised during normal business hours upon reasonable prior written notice of not less than 45 days to SymBio in the location where the records are maintained. The auditor shall execute a reasonable written confidentiality agreement with SymBio and shall disclose to Chimerix only such information as is reasonably necessary to provide Chimerix with information regarding any actual or potential discrepancies between amounts reported and actually paid and amounts payable under this Agreement. The auditor shall send a copy of the report to SymBio at the same time it is sent to Chimerix. The report sent to both Parties shall include the methodology and calculations used to determine the results. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Chimerix shall bear the full cost of such audit unless such audit discloses an underpayment by SymBio of more than the greater of [*]% of the amount due for any calendar year under this Agreement or [*] Dollars ($[*]), in such case, SymBio shall bear the full cost of such audit and shall promptly remit to Chimerix the amount of any underpayment. If such audit discloses an overpayment by SymBio, then SymBio shall deduct the amount of such overpayment from amounts otherwise owed to Chimerix under this Agreement.

5.5 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest at a rate per annum that is [*] basis points (*i.e.*, [*] percentage points) above the then-current prime rate quoted by Citibank in New York City for the period from the due date for payment until the date of actual payment; *provided, however,* that

in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Chimerix from exercising any other rights it may have as a consequence of the lateness of any payment.

ARTICLE 6

CONFIDENTIALITY AND PUBLICATION

6.1 Confidential Information. Except to the extent expressly authorized by this Agreement, each Party (in such capacity, the **"Receiving Party"**) agrees that, during the Term and for 7 years thereafter (or, with respect to any Confidential Information that constitutes a trade secret of the Disclosing Party (as defined below), until such time as the relevant Confidential Information no longer constitutes a trade secret), it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement or any other written agreement between the Parties, any Confidential Information furnished or made available to it by or on behalf of the other Party (in such capacity, the **"Disclosing Party"**). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates', employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information.

6.2 Exceptions. Confidential Information shall not include any information that the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (b) is known by the Receiving Party or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party or any of its Affiliates, without the use of Confidential Information of the Disclosing Party. Any combination of features or disclosures shall not be deemed to fall within the exclusions set forth in the preceding clauses (a) and (b) merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

6.3 Authorized Disclosure. Notwithstanding the provisions of Section 6.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights as permitted by this Agreement;

(b) enforcing such Party's rights under this Agreement and in performing its obligations under this Agreement;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with applicable court orders, Applicable Laws, rules or regulations, or the listing rules of any exchange on which the Receiving Party's securities are traded;

(e) disclosure to Affiliates, actual and potential Third-Party licensees and sublicensees of the Receiving Party, and employees, consultants, subcontractors, agents, or other business partners of the Receiving Party who, in each case, have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential licensee or sublicensee, employee, consultant, subcontractor, agent, or other business partner, agrees to be bound by terms of confidentiality and non-use comparable in scope to those set forth in this Article 6; and

(f) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third-Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use.

Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 6.3(c) or 6.3(d), it shall, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Receiving Party agrees to take all reasonable action to avoid disclosure of Confidential Information hereunder.

6.4 Publications. SymBio and its Affiliates shall have the right to publish or disclose the results of their development activities, including clinical trials, with respect to the Compounds and Products in the Field, provided that Chimerix shall have the right to review and comment on any such proposed publication or disclosure to the extent the publication or disclosure is related to, *inter alia*, pre-clinical trial results, clinical trial results or safety issues ("Drafts"). Before a Draft is submitted for publication or disclosure (other than oral presentation materials and abstracts, which are specifically addressed below), SymBio shall deliver a complete copy to Chimerix at least 20 days prior to submitting the material to a publisher or initiating such other disclosure, and Chimerix shall review any such material and give its comments to SymBio within 10 days of the delivery of such material to Chimerix, which comments shall be considered by SymBio in good faith. With respect to oral presentation materials and abstracts, SymBio shall deliver a complete copy to Chimerix at least 10 days prior to the anticipated date of the presentation, and Chimerix shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to SymBio with appropriate comments, if any, but in no event later than 5 days from the date of delivery to Chimerix, which comments shall be considered by SymBio in good faith. SymBio shall comply, or cause its Affiliate to comply (as applicable), with Chimerix's requests to delete references to Chimerix's Confidential Information in any such material and agrees to delay any submission for publication or other public disclosure for a period of up to an additional 60 days for the purpose of preparing and filing appropriate patent applications. In addition, SymBio shall comply with Chimerix's request to delete from such materials any unpublished chemical structure

of any Compound or any unpublished method of synthesis of any Compound. Chimerix shall not publish any information relating to Compounds or Products in the Field without the prior written consent of SymBio (such consent not to be unreasonably withheld or delayed); *provided*, *however*, that, notwithstanding the foregoing or any other provision of this Agreement to the contrary, Chimerix or its academic collaborator(s) shall be free to publish the results of research and development activities with respect to Chimerix Products, whether conducted before or after the Effective Date provided that such publications do not refer to or disclose the Confidential Information of SymBio. To the extent practicable under the circumstances and to the extent Chimerix has the right and ability to do so, Chimerix shall use reasonable efforts to provide SymBio with the opportunity to review and comment on any proposed publication of the results of research and development activities with respect to Chimerix Products and shall comply with SymBio's request to delete references to SymBio's Confidential Information; *provided*, *however*, that the failure to provide SymBio with the opportunity to review and comment on any such proposed publication by an academic collaborator of Chimerix (even if one or more Chimerix employees is a named co-author of such publication or Chimerix's contributions to such research and development are acknowledged in such publication) that does not contain or refer to the Confidential Information of SymBio shall not constitute a breach of Chimerix's obligation under this sentence if such academic collaborator has the right, by contract, institutional policy or otherwise, to make such publication.

6.5 Publicity.

(a) Press Releases. No later than one (1) Business Day following the Effective Date, the Parties shall issue a joint press release, in substantially the form attached hereto as **Exhibit E**, announcing the execution of this Agreement. Except as required (as such requirement is reasonably determined by such Party) by applicable securities laws or the listing rules of any stock exchange on which securities issued by a Party or its Affiliates are traded, neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, respond to queries by any exchange on which such Party's securities are traded, or issue press releases, so long as any such public statement, response, or press release is not inconsistent with prior public disclosures or public statements made in accordance with this Section 6.5 and that do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall use reasonable efforts to provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text, unless the proposed text is substantially the same as that used in any prior public disclosure, press release or public statement made in accordance with this Section 6.5.

(b) Filing of this Agreement. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with any securities authority or with any stock exchange on which securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential

treatment for the terms proposed to be redacted; provided that each Party shall ultimately retain control over what information to disclose to any securities authority or stock exchange, as the case may be, and provided further that the Parties shall use their reasonable efforts to file redacted versions with any governing bodies that are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor any of its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to any securities authority or stock exchange.

6.6 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 6 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Mutual Non-Disclosure Agreement between the Parties dated August 27, 2018. Any information disclosed by a Party pursuant to any such prior agreement shall be deemed Confidential Information of such Party for purposes of this Agreement.

ARTICLE 7

REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

7.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the Person or Persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; and (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

7.2 Chimerix Representations and Warranties. Chimerix represents and warrants to SymBio that as of the Effective Date of this Agreement:

(a) **Exhibit A** attached hereto contains a true and complete list of the Chimerix Patent Rights existing on the Effective Date. The Chimerix Patent Rights listed in **Exhibit A** include all of the Patent Rights Controlled by Chimerix as of the Effective Date that Cover the Compound or any compound Controlled by Chimerix as of the Effective Date that is known to be a Converting Compound, or the manufacture, use, sale, offer for sale or import of any of the foregoing;

(b) Chimerix has: (i) the right to grant the licenses and other rights that it purports to grant to SymBio herein; and (ii) not granted to any Third Party any license or other right with respect to any Compound, Product or Chimerix Technology that conflicts with the license and rights granted to SymBio herein;

(c) there are no agreements in effect as of the Effective Date between Chimerix and a Third Party under which rights in the Chimerix Technology are being licensed to Chimerix;

(d) Chimerix is the sole and exclusive owner of all right, title and interest in and to the Chimerix Patent Rights in existence on the Effective Date;

(e) to the best of Chimerix's knowledge, having made reasonable inquiries, the issued and unexpired claims included in the Chimerix Patent Rights existing as of the Effective Date are valid and enforceable;

(f) to the best of Chimerix's knowledge, having made reasonable inquiries, no reexamination, interference, invalidity, opposition, nullity or similar claim or proceeding is pending or threatened with respect to any Chimerix Patent Right;

(g) to the best of Chimerix's knowledge, neither the development of Compound or Product, nor the manufacture of Compound or Product for use in development activities, Infringes the Patent Rights of any Third Party or misappropriates the proprietary information of any Third Party;

(h) neither Chimerix nor any of its Affiliates has instituted any claim against a Third Party alleging that such Third Party is infringing Chimerix Patents or misappropriating Chimerix Know-How, and, to Chimerix's knowledge, no Third Party is infringing Chimerix Patents or misappropriating Chimerix Know-How;

(i) the rights in the Chimerix Technology granted to SymBio under this Agreement are sufficient to enable SymBio or its appointed subcontractor to manufacture the Compound and Product as the Compound and Product have been manufactured by or on behalf of Chimerix as of the Effective Date;

(j) there are no claims, judgments or settlements against or owed by Chimerix (or any of its Affiliates) with respect to the Chimerix Technology, and Chimerix is not a party to any legal action, suit or proceeding relating to the Chimerix Technology or any Compound or Product, nor has Chimerix received any written communication from any Third Party, including any Regulatory Authority or other government agency, threatening such action, suit or proceeding;

(k) all tangible or recorded information and data provided by or on behalf of Chimerix to SymBio related to Compound or Product on or before the Effective Date in contemplation of this Agreement was and is true, accurate and complete in all material respects, and Chimerix has not failed to disclose, or failed to cause to be disclosed, any such information or data related to Compound or Product in its possession and Control that would cause the information and data that has been disclosed to be misleading in any material respect;

(l) neither Chimerix nor any of its Affiliates has obtained, or filed for, any INDs (other than the Compound INDs and its progeny that have been disclosed to SymBio), NDAs or Marketing Approvals for any Compound or Product in the Field, and, to Chimerix's knowledge, no other Person has obtained, or filed for, any INDs, NDAs or Marketing Approvals for any Compound or Product in the Field in the Territory;

(m) at the time of delivery to SymBio, the Inventory (other than any reference standards) (i) shall be free and clear of any liens or encumbrances, (ii) shall conform to applicable specifications, and (iii) shall have been manufactured in compliance with U.S. GMP, and (iv) shall not be adulterated or misbranded within the meaning of the Act. Certificates of analysis and certificates of conformance shall be accurate and complete. Except as expressly set forth in this Section 7.2(m), the Inventory is provided on an as is/where is basis without any representation or warranty of any kind;

(n) all research and development (including non-clinical studies and clinical trials) conducted by or on behalf of Chimerix or any of its Affiliates related to the Compounds or Products prior to the Effective Date was conducted in compliance in all material respects with all Applicable Laws and, to the extent applicable, U.S. GLP, U.S. GCP or U.S. GMP;

(o) neither Chimerix nor any of its Affiliates is debarred or disqualified under the Act or comparable Applicable Laws outside of the United States;

(p) neither Chimerix nor any of its Affiliates has employed or otherwise used in any capacity, in connection with the development or manufacture of Compound or Product, the services of any Person debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof;

(q) Chimerix and, to its knowledge, its directors, officers, employees, and any agent, representative, subcontractor or other Third Party acting for or on such its behalf, has not, directly or indirectly, offered, paid, promised to pay, or authorized such offer, promise or payment, of anything of value, to any Person for the purposes of obtaining or retaining business through any improper advantage in connection with the development, commercialization or exploitation of a Product, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption, and Chimerix’s books, accounts, records and invoices related to the Product are complete and accurate;

(r) Chimerix has not violated the FCPA or Export Control Laws in connection with the development of the Compound prior to the Effective Date of this Agreement; and

(s) neither Chimerix nor any of its Affiliates (or any of their respective employees and contractors), in connection with the exercise of Chimerix's rights or performance of Chimerix's obligations under this Agreement, has violated any Export Control Laws or any terms and conditions of any applicable export license or authorization.

7.3 Chimerix Covenants. In addition to any covenants made by Chimerix elsewhere in this Agreement, Chimerix hereby covenants to SymBio that during the Term, Chimerix shall not grant any Third Party any license or other right with respect to any Compound, Product, Chimerix Technology, or Joint Invention in derogation of the license and other rights granted to SymBio hereunder.

Neither Chimerix nor any of its Affiliates shall employ or use the services of any Person who is debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign

equivalent thereof, in connection with activities relating to any Compound or Product; and in the event that Chimerix becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to Chimerix or any of its Affiliates with respect to any activities relating to any Compound or Product under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof, Chimerix shall immediately notify SymBio in writing and Chimerix shall cease, or cause its Affiliate to cease (as applicable), employing, contracting with, or retaining any such Person to perform any services relating to any Compound or Product.

Chimerix further covenants that neither Chimerix nor any of its Affiliates (or any of their respective employees and contractors) shall, in connection with the exercise of its rights or performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, Entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party (collectively, **"Public Official"**) or other Person for the purpose of obtaining or retaining business for or with, or directing business to, any Person, including Chimerix and its Affiliates, nor shall Chimerix or any of its Affiliates directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to any Public Official or any other Person in connection with the exercise of Chimerix's rights or performance of Chimerix's obligations under this Agreement.

7.4 SymBio Representations and Warranties. SymBio represents and warrants to Chimerix that as of the Effective Date of this Agreement neither SymBio nor any of its Affiliates is debarred or disqualified under the Act or comparable Applicable Laws outside the United States.

7.5 SymBio Covenants. In addition to any covenants made by SymBio elsewhere in this Agreement, SymBio hereby covenants to Chimerix as follows:

(a) neither SymBio nor any of its Affiliates shall employ or use the services of any Person who is debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof, in connection with activities relating to any Compound or Product; and in the event that SymBio becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to SymBio or any of its Affiliates with respect to any activities relating to any Compound or Product, SymBio shall immediately notify Chimerix in writing and SymBio shall cease, or cause its Affiliate to cease (as applicable), employing, contracting with, or retaining any such Person to perform any services relating to any Compound or Product;

(b) neither SymBio nor any of its Affiliates (or any of their respective employees and contractors) shall, in connection with the exercise of its rights or performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving

of anything of value to a Public Official or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, including SymBio and its Affiliates, nor shall SymBio or any of its Affiliates directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or any other Person;

(c) neither SymBio nor any of its Affiliates (or any of their respective employees and contractors), in connection with the exercise of SymBio's rights or performance of SymBio's obligations under this Agreement, violate Export Control Laws or any terms and conditions of any applicable export license or authorization;

(d) neither SymBio nor any of its Affiliates (or any of their respective employees and contractors), in connection with the exercise of SymBio's rights or performance of SymBio's obligations under this Agreement, shall cause Chimerix to be in violation of applicable anti-corruption laws (including the FCPA) or Export Control Laws; and

(e) SymBio shall immediately notify Chimerix if it has any information or suspicion that there may be a violation of applicable anti-corruption laws (including the FCPA) or Export Control Laws in connection with the exercise of SymBio's rights or performance of SymBio's obligations under this Agreement. Chimerix shall have the right, upon reasonable prior written notice and during SymBio's regular business hours, to audit SymBio's books and records in the event of a suspected violation of any of the covenants in this Section. SymBio will fully cooperate with Chimerix on such audit.

7.6 Performance by Affiliates, Sublicensees and Subcontractors. The Parties recognize that each Party may perform some or all of its obligations or exercise some or all of its rights under this Agreement through one or more Affiliates, subcontractors, agents, or other business partners, or, in the case of SymBio and subject to Section 2.2, Sublicensees; *provided*, in each case, that (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such delegation or subcontracting, and (b) each such Affiliate, subcontractor, agent or other business partner, or Sublicensee undertakes in writing obligations of confidentiality and non-use regarding Confidential Information and ownership of Inventions that are substantially the same as those undertaken by the Parties pursuant to Article 6 and Section 8.1; and *provided, further,* that such Party shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor, agent, or other business partner or Sublicensee.

7.7 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS." Except as expressly set forth in this Agreement, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

7.8 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH BY EITHER PARTY OF Article 6, OR IN THE CASE OF FRAUD OR INTENTIONAL MISCONDUCT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however,* that this Section 7.8 shall not be construed to limit either Party's indemnification obligations under Article 10.

ARTICLE 8

INTELLECTUAL PROPERTY

8.1 Ownership. Except as otherwise expressly agreed by the Parties in writing, (a) a Party shall have and retain all right, title and interest in any Invention discovered, generated, conceived or reduced to practice solely by one or more employees or agents of such Party or its Affiliates or other Persons acting under its authority and (b) the Parties shall jointly own rights in any Invention discovered, generated, conceived or reduced to practice jointly by one or more employees or agents of each Party or its Affiliates or other Persons acting under its authority (**"Joint Inventions"**) and Patent Rights therein (**"Joint Patent Rights"**). Subject to the rights and licenses granted under this Agreement, each Party shall have the right to practice and use, and grant licenses to practice and use, any Joint Inventions and Joint Patent Rights without the other Party's consent and has no duty to account to the other Party for such practice, use or license, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting. This Section shall not be interpreted to allow Chimerix to discover, develop, make, have made, use, sell, have sold, offer for sale, market, export, import or otherwise commercialize any Compounds or Products in the Field nor to allow SymBio to do the same outside the Field.

8.2 Patent Prosecution and Maintenance.

(a) Chimerix Patent Rights. Chimerix shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance of Chimerix Patent Rights at Chimerix's sole expense and by counsel of its choice. In the event that Chimerix desires to abandon or cease prosecution or maintenance of any Chimerix Patent Right in a country (other than a Chimerix Patent Right the claims of which are limited to methods of use of Compound or Product outside the Field), Chimerix shall provide written notice to SymBio of such intention to abandon promptly after Chimerix makes such determination (which notice shall be given no later than 90 days prior to the next deadline for any action that must be taken with respect to such Chimerix Patent Right in the relevant patent office). In such case, SymBio shall have the right, in its discretion, exercisable upon written notice to Chimerix delivered no later than 30 days after receipt of notice from Chimerix, to assume responsibility for prosecution and maintenance of such Chimerix Patent Right in such country, at its sole cost and expense and by counsel of its own choice.

(b) Joint Patent Rights. Chimerix shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance of Joint Patent Rights at Chimerix's sole expense and by counsel of its choice. In the event that Chimerix desires to abandon or cease prosecution or maintenance of any Joint Patent Right, Chimerix shall provide written notice

to SymBio of such intention to abandon promptly after Chimerix makes such determination (which notice shall be given no later than 90 days prior to the next deadline for any action that must be taken with respect to such Joint Patent Right in the relevant patent office). In such case, SymBio shall have the right, in its discretion, exercisable upon written notice to Chimerix delivered no later than 30 days after receipt of notice from Chimerix, to assume responsibility for prosecution and maintenance of such Joint Patent Right in the Field in the Territory, at its sole cost and expense and by counsel of its own choice. If SymBio requests that Chimerix file a patent application claiming a particular Joint Invention in a particular country in which Chimerix has not done so, and if Chimerix does not file a patent application claiming such Joint Invention in such country within a reasonable time period following its receipt of such notice from SymBio, SymBio shall have the right to assume responsibility for the preparation, filing, prosecution and maintenance of Joint Patent Rights claiming such Joint Invention in such country in accordance with this Section 8.1.

(c) SymBio Patent Rights. SymBio shall have the sole right, but not the obligation, to control the preparation, filing, prosecution and maintenance of SymBio Patent Rights, at SymBio's sole expense and by counsel of its choice.

(d) Cooperation of the Parties. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patent Rights under this Agreement and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect to any Patent Right. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to effectuate the ownership of Inventions, including Joint Inventions and Joint Patent Rights, as set forth in Section 8.1, and to enable the other Party to apply for and to prosecute patent applications in any country in accordance with the foregoing provisions of this Section 8.1; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may be reasonably expected to affect the preparation, filing, prosecution or maintenance of any such patent applications.

8.3 Interference, Opposition, Invalidation, Reexamination and Reissue.

(a) Chimerix Patent Rights. Chimerix shall, within 10 days of learning of any request for, or filing or declaration of, any interference, opposition, invalidation, reissue or reexamination relating to claims of the Chimerix Patent Rights, inform SymBio thereof.

(i) Chimerix Field Patent Rights. With respect to any request for, or filing or declaration of, any interference, opposition, invalidation, reissue or reexamination with respect to Chimerix Field Patent Rights, Chimerix shall have the first right (in its discretion) to initiate, prosecute or respond, to such action or proceeding, provided that Chimerix shall consult with SymBio with respect to any such action or proceeding and shall consider SymBio's position in good faith. In the event that Chimerix elects to initiate, prosecute or respond to any interference, opposition, invalidation, reexamination, or reissue proceeding with respect to any Chimerix Field Patent Right, the expenses thereof shall be borne solely by Chimerix. Chimerix shall not settle any interference, opposition, invalidation, reissue or reexamination action or proceeding relating to any Chimerix Field Patent Right without the prior written consent of SymBio, which consent shall not be unreasonably withheld. Chimerix shall keep SymBio informed of developments in any such action or proceeding involving any Chimerix Field Patent Right. Chimerix shall promptly (but in

any event within a reasonable time period in advance of any applicable deadline) inform SymBio in the event that Chimerix elects not to initiate, prosecute or respond to any interference, opposition, invalidation, reissue or reexamination relating to any Chimerix Field Patent Right, and in such case, SymBio shall have the right to do so (in SymBio's discretion), at its cost and expense. SymBio shall not settle any interference, opposition, invalidation, reissue or reexamination action or proceeding relating to any Chimerix Field Patent Right without the prior written consent of Chimerix, which consent shall not be unreasonably withheld. SymBio shall keep Chimerix informed of developments in any such action or proceeding involving any Chimerix Field Patent Rights.

(ii) Other Chimerix Patent Rights. With respect to any request for, or filing or declaration of, any interference, opposition, invalidation, reissue or reexamination with respect to any Chimerix Patent Rights other than Chimerix Field Patent Rights, Chimerix shall have the sole right (in its discretion) to initiate, prosecute or respond, to such action or proceeding, at Chimerix's sole expense. Chimerix shall keep SymBio informed of developments in any such action or proceeding involving any such Chimerix Patent Right.

(b) Joint Patent Rights. Each Party shall, within 10 days of learning of such event, inform the other Party of any request for, or filing or declaration of, any interference, opposition, invalidation, reissue or reexamination with respect to Joint Patent Rights.

(i) Chimerix First Right. With respect to any request for, or filing or declaration of, any interference, opposition, invalidation, reissue or reexamination with respect to claims of the Joint Patent Rights, Chimerix shall have the first right (in its discretion) to initiate, prosecute or respond, to such action or proceeding, provided that Chimerix shall consult with SymBio with respect to any such action or proceeding and shall consider SymBio's position in good faith. In the event that Chimerix elects to initiate, prosecute or respond to any interference, opposition, invalidation, reexamination, or reissue proceeding with respect to any Joint Patent Claim, the expenses thereof shall be borne solely by Chimerix. Chimerix shall not settle any interference, opposition, invalidation, reissue or reexamination action or proceeding relating to any Joint Patent Claim without the prior written consent of SymBio, which consent shall not be unreasonably withheld. Chimerix shall keep SymBio informed of developments in any such action or proceeding involving any Joint Patent Claim.

(ii) SymBio Back-Up Right. Chimerix shall promptly (but in any event within a reasonable time period in advance of any applicable deadline) inform SymBio in the event that Chimerix elects not to initiate, prosecute or respond to any interference, opposition, invalidation, reissue or reexamination relating to any Joint Patent Claim, and in such case, SymBio shall have the right to do so (in Chimerix's discretion), at its cost and expense. SymBio shall not settle any interference, opposition, invalidation, reissue or reexamination action or proceeding relating to any Joint Patent Claim without the prior written consent of Chimerix, which consent shall not be unreasonably withheld. SymBio shall keep Chimerix informed of developments in any such action or proceeding involving any Relevant Joint Patent Claim.

(c) SymBio Patent Rights. SymBio shall have the sole right, in its discretion, to handle any interference, opposition, invalidation, reissue, or reexamination proceeding relating to SymBio Patent Rights, and Chimerix shall have no rights in connection therewith.

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

8.4 Enforcement and Defense of Patent Rights. Each Party shall notify the other Party in writing within 10 Business Days (except as expressly set forth below) of becoming aware of any alleged or threatened Infringement by a Third Party of any of the Chimerix Patent Rights, Joint Patent Rights or SymBio Patent Rights (**"Infringement"**), including (x) any such alleged or threatened Infringement on account of a Third Party's manufacture, use or sale of a Compound or Product in the Field, (y) any certification filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions in connection with an ANDA (an Abbreviated New Drug Application in the United States or a comparable application for Marketing Approval under Applicable Law in any country other than the United States) or other NDA for a Product in the Field (a **"Patent Certification"**), and (z) any declaratory judgment action filed by a Third Party that is developing, manufacturing or commercializing a Compound or Product in the Field alleging the invalidity, unenforceability or non-infringement of any of the Chimerix Patent Rights, Joint Patent Rights or SymBio Patent Rights ((x)-(z), collectively, **"SymBio Competitive Infringement"**); *provided, however,* that each Party shall notify the other Party of any Patent Certification regarding any Chimerix Patent Right or Joint Patent Right that it receives, and provide the other Party with a copy of such Patent Certification, within five (5) days of receipt.

(a) Chimerix Patent Rights.

(i) Chimerix Field Patent Rights.

(1) SymBio Competitive Infringement. SymBio shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to SymBio Competitive Infringement of a Chimerix Field Patent Right in any country, at SymBio's own expense and by counsel of its own choice, and Chimerix shall have the right to be represented in any such action or proceeding, at Chimerix's own expense and by counsel of its own choice. If SymBio fails to bring any such action or proceeding with respect to SymBio Competitive Infringement of any Chimerix Field Patent Right in such country within 90 days following the notice of alleged SymBio Competitive Infringement, Chimerix shall have the right to bring (or defend) and control any such action at its own expense and by counsel of its own choice, and SymBio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice; *provided, however,* that if the applicable SymBio Competitive Infringement is the result of SymBio's receipt of a Patent Certification with respect to a Chimerix Field Patent Right in a country, SymBio shall notify Chimerix of SymBio's decision to bring (or defend) and control any action or proceeding in such country within 10 days of SymBio's receipt of such Patent Certification with respect to a Chimerix Field Patent Right, after which time, Chimerix shall have the right to bring (or defend) and prosecute such action, and SymBio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(2) Other Infringement. Chimerix shall have the sole right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to any Infringement of any Chimerix Field Patent Right that is not SymBio Competitive Infringement in any country, at its own expense and by counsel of its own choice.

(ii) Other Chimerix Patent Rights. Chimerix shall have the sole right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to any

Infringement (including SymBio Competitive Infringement) of any Chimerix Patent Right that is not a Chimerix Field Patent Right in any country, at its own expense and by counsel of its own choice, and, only if and to the extent such action or proceeding is with respect to SymBio Competitive Infringement in such country, SymBio shall have the right to be represented in any such action or proceeding, at SymBio's own expense and by counsel of its own choice. If Chimerix fails to bring (or defend) any such action or proceeding with respect to SymBio Competitive Infringement of any such Chimerix Patent Right in such country within 90 days following the notice of alleged SymBio Competitive Infringement, SymBio may request that Chimerix permit SymBio to bring (or defend) and control any such action at its own expense and by counsel of its own choice. Chimerix shall consider any such request in good faith but shall have the right to withhold such consent in its sole discretion. However, if (A) such SymBio Competitive Infringement in such country is occurring more than 10 years after the First Commercial Sale of the Product with which such SymBio Competitive Infringement is competing in such country, (B) a Generic Version of such Product is on the market in such country (regardless of the market share obtained by such Generic Version), and (C) Chimerix withholds its consent to permit SymBio to bring (or defend) and control such action, then, for the remainder of the Royalty Term for such Product in such country, the royalties payable by SymBio under Section 4.4 with respect to Net Sales of such Product in such country shall be reduced by [*]%.

(b) Joint Patent Rights.

(i) SymBio Competitive Infringement. SymBio shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to SymBio Competitive Infringement of any Joint Patent Right, at its own expense and by counsel of its own choice, and Chimerix shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If SymBio fails to bring any such action or proceeding with respect to SymBio Competitive Infringement of any Joint Patent Right within 90 days following the notice of alleged Infringement, Chimerix shall have the right to bring (or defend) and control any such action at its own expense and by counsel of its own choice, and SymBio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice; *provided, however,* that if the applicable SymBio Competitive Infringement is the result of SymBio's receipt of a Patent Certification with respect to a Joint Patent Right, SymBio shall notify Chimerix of SymBio's decision to bring (or defend) and control any action or proceeding within 10 days of SymBio's receipt of such Patent Certification with respect to a Joint Patent Right, after which time, Chimerix shall have the right to bring (or defend) and prosecute such action, and SymBio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) Chimerix Competitive Infringement. Chimerix shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Infringement of any Joint Patent Right to the extent the Infringement is competitive with a Chimerix Product being developed or commercialized by Chimerix or any of its Affiliates or Third-Party licensees or sublicensees (**"Chimerix Competitive Infringement"**), at its own expense and by counsel of its own choice, and SymBio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Chimerix fails to bring any such action or proceeding with respect to Chimerix Competitive Infringement of any Joint Patent Right within

90 days following the notice of alleged Infringement, SymBio shall have the right to bring (or defend) and control any such action at its own expense and by counsel of its own choice, and Chimerix shall have the right, at its own expense, to be represented in any such action by counsel of its own choice; *provided, however,* that if the applicable Chimerix Competitive Infringement is the result of Chimerix's receipt of a Patent Certification with respect to a Joint Patent Right, Chimerix shall notify SymBio of Chimerix's decision to bring (or defend) and control any action or proceeding within 10 days of Chimerix's receipt of such Patent Certification with respect to a Chimerix Patent Right, after which time Chimerix shall have the right to bring (or defend) and prosecute such action, and SymBio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(iii) Other Infringement. The Parties shall mutually agree on a case-by-case basis (A) whether to bring (or defend) and control any action or proceeding with respect to Infringement of any Joint Patent Right to the extent the Infringement is neither SymBio Competitive Infringement nor Chimerix Competitive Infringement, (B) which Party would bring (or defend) and control such action, and (C) how the expenses of, and any recovery from, any such action would be allocated.

(c) SymBio Patent Rights. SymBio shall have the sole right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Infringement of any SymBio Patent Right at its own expense and by counsel of its own choice.

(d) Cooperation. In the event a Party brings (or defends) an infringement action in accordance with this Section 8.4, or in the event a Party is entitled to bring (or defend) an infringement action in accordance with this Section 8.4 but lacks standing to do so, the other Party shall cooperate fully, including, if required to bring (or defend) such action, the furnishing of a power of attorney or being named as a party. Neither Party shall enter into any settlement or compromise of any action under this Section 8.4 that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

(e) Recovery. Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized by a Party as a result of any action or proceeding pursuant to this Section 8.4, whether by way of settlement or otherwise, shall be applied first to reimburse the documented out-of-pocket legal expenses of the Party that brought (or defended) and controlled such action or proceeding incurred in connection with such action or proceeding, and second to reimburse the documented out-of-pocket legal expenses of the other Party incurred in connection with such action or proceeding, and any remaining amounts shall be retained by the Party that brought (or defended) and controlled such action; *provided, however,* that:

(i) any recovery realized by SymBio as a result of any action brought (or defended) and controlled by SymBio pursuant to Section 8.4(a)(i)(1) or Section 8.4(b)(i) (after reimbursement of the Parties' documented out-of-pocket legal expenses relating to the action or proceeding) shall be allocated as follows:

(1) compensatory damages shall be treated as Net Sales of Products in the quarter in which such damages are received for purposes of Section 4.4; and

(2) non-compensatory damages shall be divided [*]% to SymBio and [*]% to Chimerix; and

(ii) any recovery realized by Chimerix as a result of any action brought (or defended) and controlled by Chimerix pursuant to Section 8.4(a)(ii) (after reimbursement of the Parties' documented out-of-pocket legal expenses relating to the action or proceeding) shall be allocated as follows:

(1) all compensatory and non-compensatory damages that are specifically attributable to SymBio Competitive Infringement shall be divided [*]% to Chimerix and [*]% to SymBio; and

(2) all compensatory and non-compensatory damages that are not specifically attributable to SymBio Competitive Infringement shall belong to Chimerix.

8.5 Patent Term Extensions.

(a) Chimerix Patent Rights. SymBio shall have the right to determine the Chimerix Patent Rights for which it will apply for patent extension in any country or region for any Product in the Field, subject to Chimerix's prior written consent, not to be unreasonably withheld, provided that Chimerix may withhold such consent in its sole discretion with respect to any Chimerix Patent Right in any country or region: (i) that Covers a Chimerix Product; or (ii) for which Chimerix (or its Affiliate or Third-Party licensee or sublicensee) has already applied for or received patent extension for any compound that is not a Compound or product that is not a Product. If Chimerix grants such consent, SymBio shall file for any such extension at SymBio's cost and expense. Chimerix shall provide all reasonable assistance to SymBio in connection with such filings with respect to which Chimerix provides its consent, provided that SymBio shall pay or reimburse any out-of-pocket costs incurred by Chimerix in providing such assistance.

(b) Joint Patent Rights. SymBio shall have the right to determine the Joint Patent Rights for which it will apply for patent extension in any country or region for any Product in the Field, and SymBio shall file for any such extension at SymBio's cost and expense; *provided, however,* that, solely in the case of Joint Patent Rights that do not claim or Cover any Product in the Field, Chimerix shall have the right to determine those of such Joint Patent Rights for which it will apply for patent extension in any country or region for a Chimerix Product, and Chimerix shall file for any such extension at Chimerix's cost and expense. Each Party shall provide all reasonable assistance to the other Party in connection with such filings, provided that the Party filing for any such extension shall pay or reimburse any out-of-pocket costs incurred by the other Party in providing such assistance.

(c) SymBio Patent Rights. SymBio shall have the sole right to apply for extension of any SymBio Patent Right in any country or region for any product, including any Product in the Field, at SymBio's sole cost and expense.

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

8.6 Infringement of Third-Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the manufacture, use, sale or importation of any Compound or Product Infringes or may Infringe the intellectual property rights of such Third Party. Neither Party shall have the right to settle any patent infringement litigation under this Section 8.6 in a manner that diminishes the rights or interests of the other Party without the written consent of such other Party (which shall not be unreasonably withheld).

8.7 Marking. To the extent required by applicable law, SymBio shall, and shall cause its Related Parties to, mark all Products made, used or sold in the Field, or their containers, with the number of each issued Chimerix Patent Right that applies to such Product; *provided, however,* that in any event SymBio shall, and shall cause its Related Parties to, mark all Products made, used or sold in the Field, or their containers, with the number of each issued Chimerix Patent Right that applies to such Product.

8.8 Trademarks. SymBio shall have the right to commercialize the Product in the Field in the Territory with those trademarks of SymBio that are associated with SymBio's name or identity ("**SymBio Housemarks**") and any other trademarks and trade names it determines appropriate, which may vary by country or within a country (the "**Product Marks**"). SymBio shall own all rights in, and shall have the right to register and maintain, the SymBio Housemarks and the Product Marks in the countries and regions that it determines reasonably necessary, at its own cost and expense, and all goodwill therein or relating thereto shall accrue to SymBio. Neither Party shall use, or shall permit its Affiliates, sublicensees, subcontractors, and agents to use, any trademark of the other Party in connection with the commercialization of the Products except as expressly set forth in this Agreement or with the prior written consent of such other Party.

8.9 Registration of Exclusive License. Within 30 days of the Effective Date, Chimerix shall file, and shall cause its relevant Affiliates to file (as the case may be), a request at the Japan Patent Office (**"JPO"**) to register as a registered exclusive license (a *Senyo-Jisshiken* under Section 77 of the Japanese Patent Law or a *Kari-Senyo-Jisshiken* under Section 34-2 of the Japanese Patent Law), along with equivalent requests for registration (where applicable) at all relevant patent offices in the Territory, SymBio's exclusive license under the Chimerix Patent Rights to develop, package, manufacture, and commercialize the Product in the Field in the Territory in accordance with this Agreement. For clarity, during the Term, Chimerix shall not grant a license in respect of the Product under the Chimerix Patent Rights in the Field in the Territory to any Third Party or Affiliate of Chimerix, in each case (Third Party or Affiliate) in conflict with the license granted to SymBio under this Agreement, nor register such license to a Third Party or Affiliate of Chimerix as a *Senyo-Jisshiken*, *Kari-Senyo-Jisshiken* or otherwise.

ARTICLE 9

TERM AND TERMINATION

9.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with this Article 9, continue until the expiration of the last-to-expire of all Royalty Terms hereunder (the **"Term"**).

9.2 Termination for Material Breach.

(a) Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within 90 days (or 30 days with respect to any payment breach) after notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of such 90-day (or 30-day with respect to any payment breach) period unless the breaching Party has cured such breach prior to the end of such period. Any right to terminate under this Section 9.2(a) shall be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 11 with respect to the alleged breach. Such stay and tolling shall continue until such dispute has been resolved in accordance with Article 11.

(b) For clarity, in the event of material breach of this Agreement by Chimerix that is not cured within the applicable notice period set forth in Section 9.2(a), SymBio, at its sole discretion, may either:

(i) terminate this Agreement in accordance with Section 9.2(a) (in addition to pursuing any remedy that may be available to SymBio at law or in equity as a result of Chimerix's breach of this Agreement); or

(ii) elect (A) not to terminate this Agreement, (B) to retain the license granted under Section 2.1, subject to all terms and conditions hereof, and (C) pursue any remedy that may be available to SymBio at law or in equity as a result of Chimerix's breach of this Agreement, without prejudice to SymBio's right to terminate this Agreement at a later date pursuant to Section 9.2(a) (for that uncured material breach or any other uncured material breach of this Agreement by Chimerix) or pursuant to Section 9.3.

9.3 Termination for Patent Challenge. Chimerix shall have the right to terminate this Agreement immediately upon written notice to SymBio if SymBio or its Affiliate directly, or through assistance granted to a Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of, or the grant of a supplementary protection certificate with respect to, any Chimerix Patent Right.

9.4 At-Will Termination by SymBio. SymBio shall have the right to terminate this Agreement on a country–by-country basis for any reason, or for no reason, at any time upon 90 days' prior written notice to Chimerix.

9.5 Effect of Expiration or Termination.

(a) Expiration. Upon expiration (but not on earlier termination) of this Agreement, all licenses granted by Chimerix to SymBio that were in effect immediately prior to such expiration shall survive on a fully-paid, royalty-free, irrevocable and perpetual basis in accordance with Section 4.5.

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

(b) Any Termination. Upon any termination of this Agreement prior to its expiration, the license (on a country-by-country basis in the event of partial termination by SymBio under Section 9.4) granted to SymBio pursuant to Section 2.1 shall automatically terminate and revert to Chimerix, and all other rights and obligations of the Parties under this Agreement shall terminate, except as expressly provided below in this Section 9.5 or elsewhere in this Article 9.

(c) Termination by Chimerix Pursuant to Section 9.2(a) or 9.3 or by SymBio Pursuant to Section 9.4. Solely in the event of termination of this Agreement by Chimerix pursuant to Section 9.2(a) or Section 9.3, or by SymBio pursuant to Section 9.4, the following provisions shall apply.

(i) Effective as of such termination, SymBio shall, and it hereby does, grant to Chimerix: (A) an exclusive, worldwide, royalty-free, fully-paid, perpetual, irrevocable license (on a country-by-country basis in the event of partial termination by SymBio pursuant to Section 9.4), with the right to sublicense through multiple tiers of sublicense, under those SymBio Patent Rights that claim any Invention made solely by one or more employees or agents of SymBio or its Affiliates in the course of conducting research, development, manufacturing, regulatory or commercialization activities contemplated by this Agreement, the SymBio Know-How, and SymBio's interest in the Joint Patent Rights; (B) a non-exclusive, worldwide, royalty-free, fully-paid, perpetual, irrevocable license (on a country-by-country basis in the event of partial termination by SymBio pursuant to Section 9.4), with the right to sublicense through multiple tiers of sublicense, under Blocking Patents (defined below); and (C) an exclusive, worldwide, royalty-bearing (as specified below), perpetual, irrevocable license (on a country-by-country basis in the event of partial termination by SymBio pursuant to Section 9.3), with the right to sublicense through multiple tiers of sublicense, under Useful Patents (defined below) in each case, solely to develop, make, have made, use, sell, offer for sale, and import Compounds and Products in the Field. For purposes of this Section 9.5(c)(i), ***"Blocking Patents"*** shall mean SymBio Patent Rights *other than* those described in clause (A) of this Section 9.5(c)(i), but excluding any such SymBio Patent Right claiming any technology that was not actually used by SymBio (or any of its Related Parties) prior to termination in the development, manufacture or commercialization of Compounds or Products in the Field; and ***"Useful Patents"*** shall mean SymBio Patent Rights *other than* those described in clause (A) of this Section 9.5(c)(i) and Blocking Patents. Notwithstanding the foregoing, to the extent the Blocking Patents or Useful Patents include Patent Rights licensed to SymBio by a Third Party (other than a Sublicensee) that are subject to royalty or milestone payment obligations to such Third Party with respect to Compounds or Products, then SymBio shall so notify Chimerix, together with a true, complete and correct description of such royalty and milestone payment obligations, and the inclusion of such Blocking Patents in the license granted to Chimerix under clause (B) of this Section 9.5(c)(i) or of such Useful Patents in the license granted to Chimerix under clause (C) of this Section 9.5(c)(i), as applicable, shall be subject to Chimerix's agreeing in writing to reimburse, and promptly reimbursing, SymBio for all royalty and milestone payments that become due to such Third Party by reason of Chimerix's exercise of such Blocking Patents or Useful Patents (as applicable) in the development, manufacture or commercialization of Compounds or Products in the Field. In addition to any pass-through royalties or milestone payments that may be due to Third Parties with respect to Useful Patents licensed to SymBio by a Third Party pursuant to the preceding sentence, Chimerix shall pay to SymBio a royalty of [*]% of Net Sales (*mutatis mutandis*)

by Chimerix, its Affiliates and their respective sublicensees of any Product that is Covered by a Valid Claim of the Useful Patents, such royalties to be payable on a Product-by-Product and country-by-country basis until expiration of the last-to-expire Valid Claim of the Useful Patents Covering the manufacture, use or sale of a Product in a country. For purposes of Chimerix's royalty payment obligations with respect to the Useful Patents, the provisions of Article 5 of this Agreement shall apply, *mutatis mutandis*.

(ii) As promptly as practicable (and in any event within 90 days) after such termination, SymBio shall (on a country-by-country basis in the event of partial termination by SymBio under Section 9.4): (a) to the extent not previously provided to Chimerix, deliver to Chimerix true, correct and complete copies of all Regulatory Documentation held by SymBio or any of its Affiliates or Sublicensees, and disclose to Chimerix all previously-undisclosed SymBio Know-How; (b) transfer or assign, or cause to be transferred or assigned, to Chimerix or its designee (or to the extent not so assignable, take all reasonable actions to make available to Chimerix or its designee the benefits of) all INDs, NDAs and Marketing Approvals for Products, whether held in the name of SymBio or any of its Related Parties; and (c) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section 9.5(c)(ii) to Chimerix.

(iii) SymBio shall (on a country-by-country basis in the event of partial termination by SymBio under Section 9.4), as directed by Chimerix, either promptly wind-down any ongoing development activities with respect to Products in an orderly fashion or promptly transition such development activities to Chimerix or its designee, with due regard for patient safety and in compliance with all Applicable Laws and GCP.

(iv) Chimerix shall have the right (on a country-by-country basis in the event of partial termination by SymBio under Section 9.4), but not the obligation, to purchase from SymBio any or all usable inventory of Compounds and Products in SymBio's or its Affiliates' possession as of the date of termination. Such inventory shall be provided at a transfer price equal to SymBio's cost of such inventory.

(v) If SymBio was (on a country-by-country basis in the event of partial termination by SymBio under Section 9.4), prior to termination, manufacturing, or having manufactured on its behalf, any quantities of Compounds or Products, then at Chimerix's request, until the earlier of (a) such time as Chimerix has secured another source thereof that is able to meet Chimerix's quality and quantity requirements, and (b) 18 months after such termination, SymBio shall use Commercially Reasonable Efforts to supply, or cause to be supplied, to Chimerix such quantities thereof as Chimerix may reasonably require for the development and commercialization of Products in the Field; provided that Chimerix shall use Commercially Reasonable Efforts to secure another source of supply as soon as reasonably practicable. Such material shall be provided at a transfer price equal to SymBio's cost of such materials.

9.6 Accrued Obligations; Survival. Neither expiration nor any termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from

pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the Parties' rights and obligations under Sections 2.6, 6.1, 6.2, 6.3, 6.6, 7.7, 7.8, 8.1, 9.5, 9.6, 9.7 and 9.8, and Articles 1, 5, 10, 11 and 12 (other than 12.6 and 12.7) of this Agreement shall survive expiration or any termination of this Agreement. SymBio's right in the first sentence of Section 8.8 shall survive on a Product-by-Product and country-by-country basis after expiration of the Royalty Term for a Product in a country.

9.7 Return of Confidential Information. Within 30 days following the expiration or termination of this Agreement, except to the extent that a Party retains a license from the other Party as provided in this Article 9, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to a continuing confidentiality obligations.

9.8 Damages; Relief. Termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to hereunder.

ARTICLE 10

INDEMNIFICATION

10.1 Indemnification by SymBio. SymBio hereby agrees to save, defend, indemnify and hold harmless Chimerix, its Affiliates, its and their respective officers, directors, agents, employees, successors and assigns (the **"Chimerix Indemnitees"**), from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees (**"Losses"**), to which any Chimerix Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a **"Claim"**) to the extent such Losses arise out of or relate to (a) the gross negligence or willful misconduct of any SymBio Indemnitee (defined below), (b) the breach by SymBio of any warranty, representation, covenant or agreement made by SymBio in this Agreement, or (c) the development, manufacture, use, handling, storage, sale, offer for sale, import or other disposition by or on behalf of SymBio or any of its Related Parties of any Compound or Product, or any other exercise of the license granted to SymBio pursuant to Section 2.1 by or on behalf of SymBio or any of its Related Parties; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Chimerix Indemnitee or the breach by Chimerix of any warranty, representation, covenant or agreement made by Chimerix in this Agreement.

10.2 Indemnification by Chimerix. Chimerix hereby agrees to save, defend, indemnify and hold harmless SymBio, its Affiliates and their respective officers, directors, employees, consultants and agents (the **"SymBio Indemnitees"**) from and against any and all Losses to which any SymBio Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of or relate to (a) the gross negligence or willful misconduct of any Chimerix Indemnitee, (b) the breach by Chimerix of any warranty, representation, covenant or agreement made by Chimerix in this Agreement, (c) the development, manufacture, use, handling, storage, sale, offer for sale, import or other disposition by or on behalf of Chimerix or any of its Related Parties of any Compound or Product prior to the

Effective Date or following termination of this Agreement, (d) the conduct of the Chimerix NPP, or (e) the exercise by or on behalf of Chimerix or any of its Affiliates or Third-Party licensees or sublicensees of the license granted to Chimerix pursuant to Section 2.6 or, if applicable, any license granted to Chimerix pursuant to Section 9.5(c)(i); in each case except to the extent such Losses result from the gross negligence or willful misconduct of any SymBio Indemnitee or the breach by SymBio of any warranty, representation, covenant or agreement made by SymBio in this Agreement.

10.3 Control of Defense. In the event a Party (the **"Indemnified Party"**) seeks indemnification under Section 10.1 or 10.2, it shall inform the other Party (the **"Indemnifying Party"**) of a claim as soon as reasonably practicable after it receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Section 10.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) using counsel reasonably satisfactory to the Indemnified Party, and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. If the Indemnifying Party does not assume control of such defense within 15 days after receiving notice of the claim from the Indemnified Party, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs, including reasonable attorney fees, incurred by the Indemnified Party in defending itself within 30 days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party. If the Parties cannot agree as to the application of Section 10.1 or 10.2 to any claim, pending resolution of the dispute pursuant to Article 11, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or 10.2, as applicable, upon resolution of the underlying claim.

10.4 Insurance. Each Party shall procure and maintain insurance, including comprehensive or commercial general liability insurance (including contractual liability and product liability), adequate to cover its obligations hereunder and that is consistent with normal business practices of prudent companies similarly situated. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 10 or otherwise. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least

30 days prior to the cancellation, non-renewal or material change in such insurance that materially adversely affects the rights of the other Party hereunder.

ARTICLE 11

DISPUTE RESOLUTION

11.1 Disputes. Subject to Section 11.3, any claim, dispute, or controversy arising out of or relating to this Agreement, including as to the breach, enforcement, interpretation or validity of this Agreement (each, a **"Dispute"**) shall be referred to the Chief Executive Officer of Chimerix and the Chief Executive Officer of SymBio for attempted resolution. In the event such executives are unable to resolve such Dispute within 30 days of such Dispute being referred to them, then, upon the written request of either Party to the other Party, the Dispute shall be subject to arbitration in accordance with Section 11.2, except as expressly set forth in Section 11.3

11.2 Arbitration. Subject to Section 11.3 below, any Dispute that is not resolved under Section 11.1 within the applicable 30-day period shall be finally and exclusively settled by binding arbitration in accordance with the applicable rules of the International Chamber of Commerce (**"ICC"**) as then in effect (the **"ICC Rules"**), except to the extent any such ICC Rule conflicts with the express provisions of this Section 11.2. The Parties agree as follows:

(a) The seat, or legal place, of arbitration shall be New York City, New York. The language of the arbitration shall be English.

(b) The arbitration shall be conducted by an arbitral tribunal of three neutral arbitrators. Each Party shall appoint one (1) arbitrator in accordance with this Section 11.2. The Party initiating the arbitration shall select an arbitrator in the request for arbitration. The responding Party shall select an arbitrator within thirty (30) days after receipt of the request for arbitration. The third arbitrator, who shall act as the presiding arbitrator, shall be selected by the two Party-appointed arbitrators within forty five (45) days of the selection of the second arbitrator. Any arbitrator(s) not selected within these time periods shall be selected by the ICC. Arbitrators shall not be current or former employees or directors, or current stockholders, of either Party, any of their respective Affiliates or any Sublicensee. Each arbitrator shall have experience and familiarity with commercial licensing practices in the pharmaceutical and biotechnology industries.

(c) The parties shall be entitled to engage in an exchange of documents that are relevant and material to the outcome of the dispute, consistent with the IBA Rules on the Taking of Evidence in International Arbitration or such other rules as may be agreed by the Parties. All costs of translation associated with such exchange of documents shall be shared equally between the Parties.

(d) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law or the rules of any exchange on which a Party's securities are traded, neither a Party nor the arbitral tribunal may disclose the existence, content, or results of an arbitration without the prior written consent of both parties.

(e) The arbitral tribunal shall, in rendering an award, apply the substantive law of the State of New York, USA, in accordance with Section 12.2 and without giving effect to any conflicts of law provisions thereof that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction, and without giving effect to any of its rules or laws relating to arbitration. The award shall include a written statement describing the essential findings and conclusions upon which the award is based, including the calculation of any damages awarded. The Tribunal's authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Section 7.8, except to the extent the substantive laws of the State of New York, USA, do not permit such limitation. The award rendered by the Tribunal shall be final, binding and non-appealable (subject only to the Parties' right to request correction of any errors in computation, clerical or typographical errors, or other errors of a similar nature, and the Tribunal's right to make any such correction on its own initiative, in each case, in accordance with the Rules), and judgment upon the award may be entered in any court of competent jurisdiction.

(f) Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Tribunal; *provided, however,* the Tribunal shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, *etc.*), or the fees and costs of the ICC and the Tribunal.

11.3 Court Actions. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, Infringement or other violations of Patent Rights or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 11.2.

ARTICLE 12

MISCELLANEOUS

12.1 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the U.S. (collectively, the **"Bankruptcy Laws"**), licenses of rights to be "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain

its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

12.2 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

12.3 Entire Agreement; Amendments. This Agreement (including the Exhibits hereto) is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

12.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

12.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided*, *however*, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party (**"Third-Party Acquirer"**), whether by merger, sale of stock, sale of assets or otherwise (each, a **"Sale Transaction"**), provided that in the event of a Sale Transaction (whether this Agreement is actually assigned or is assumed by the Third-Party Acquirer or the surviving corporation resulting from such Sale Transaction by operation of law (*e.g.*, in the context of a reverse triangular merger)), intellectual property rights of the Third-Party Acquirer that existed prior to the Sale Transaction shall not be included in the technology licensed hereunder or otherwise subject to this Agreement; or

(b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein shall be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 12.5. Any assignment not in accordance with this Agreement shall be void.

12.6 Force Majeure. Except for the obligation to make payment when due, each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control, including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

12.7 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practical, implement the purposes of this Agreement.

12.8 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

12.9 Notices. All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Chimerix, to:

Chimerix, Inc.
2505 Meridian Parkway
Suite 340
Durham, NC 27713
USA
Attn: Legal Department
Facsimile No.: +1 919-806-1146

If to SymBio, to: SymBio Pharmaceuticals Limited.
Toranomon 30 Mori Building
3-2-2 Toranomon
Minato-ku, Tokyo 105-0001
Japan
Attn: Legal Department
Facsimile No.: +81 (03) 5472-3054Japan

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered, if personally delivered or sent by facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch, if sent by nationally-recognized overnight courier; or (c) on the third (3rd) Business Day following the date of mailing, if sent by mail.

12.10 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. The words “including,” “includes,” “include,” “for example,” and “e.g.” and words of similar import will be deemed to be followed by the words “without limitation,” and the word “or” has the inclusive meaning represented by the phrase “and/or.” Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such Section and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

12.11 Relationship between the Parties. The Parties’ relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party may assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

12.12 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

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

12.13 No Third-Party Rights. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other Person or Entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

12.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have duly executed this License Agreement as of the Effective Date.

Chimerix, Inc.	**SymBio Pharmaceuticals Limited**
By: /s/ Mike Sherman	By: /s/ Fuminori Yoshida
Name: Mike Sherman	Name: Fuminori Yoshida
Title: President and Chief Executive Officer	Title: President and Chief Executive Officer

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EXHIBIT A

CHIMERIX PATENT RIGHTS AS OF THE EFFECTIVE DATE

[*]

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

EXHIBIT B

INVENTORY

[*]	[*] vials
[*]	[*] kilograms#
[*]	[*] vials of [*] g [*] mg each (actual amounts provided TBD and subject to availability)

*Chimerix shall provide SymBio with all related Certificates of Analysis and Certificates of Conformance.

ǂ Chimerix shall provide SymBio with: (i) all related Certificates of Analysis and Certificates of Conformance; and (ii) all related retest data.

#[*].

Inventory provided to SymBio pursuant to this Exhibit B does not contain [*].

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EXHIBIT C

TECHNOLOGY TRANSFER PLAN

BCV IV Liquid Product Transfer Activities

Month 1	1. Chimerix to provide manufacturing information including formulation, manufacturing process and batch records 1.1. MSDS 1.2. QTPP 1.3. Raw materials 1.4. Vial, stopper and seal materials 1.5. Cleaning procedure 1.6. Development report (Liquid) 1.7. Batch records 1.7.1. Formulation 1.7.2. Process diagrams 1.7.3. Manufacturing process 1.7.4. Filling process 1.7.5. Packaging info 2. Chimerix to provide, as applicable, certificate of analysis of API, Standard, BCV IV solution as well as raw materials 3. Chimerix to provide [*] 4. Chimerix to provide Finish Product test methods and specifications (and test methods performed by product manufacturer upon receipt of API) 4.1. API test methods performed at receipt 4.1.1. Identification by IR 4.1.2. Endotoxin test 4.2. In-process test methods and specifications 4.2.1. pH 4.2.2. Assay by UV 4.3. Finished product test methods with specifications 4.3.1. Finished product specification 4.3.2. Non-compendial Finished product methods – ID by HPLC, ID by UV, Assay, Drug Related Impurities (Early-eluting and Late-eluting) 4.3.3. Identify HPLC columns 4.3.4. Working Standards and markers 4.3.5. API 4.3.6. Raw material samples
To be discussed	5. 3-Phase Approach for Analytical Method Transfer 5.1. Phase 1 – SymBio to thoroughly examine product specification and methods, obtain all equipment and supplies needed for application of methods, and interface with Chimerix on any questions related to In-process test method and specifications 5.2. Phase 2 – SymBio and/or SymBio-chosen contract facility to perform analytical methods on R&D samples of finished product and informally compare data to data generated by Lancaster and/or Chimerix. SymBio and Chimerix to assess mock transfer data and determine if more work is needed or if formal transfer should proceed 5.3. Phase 3 – SymBio and/or SymBio-chosen contract facility to draft formal method transfer protocol and acceptance criteria. SymBio/SymBio-chosen contract facility and Chimerix/Lancaster to review and approve formal method transfer protocol. Both groups will receive and test representative samples and complete methods transfer activities and report

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

To be discussed	6. SymBio to provide the name of their selected Japanese CMOs and Chimerix should assess their capabilities and review their facility and equipment validation including media fills/environmental information 7. SymBio should name their CMO 8. Chimerix to provide technical assistance to SymBio in assessing CMO's equipment and capabilities 8.1. Purchasing a [*] or smaller dedicated tank based on SymBio batch size requirement 8.2. Dedicated compounding tank [*] or smaller based on SymBio batch size requirement 8.3. IQ, PQ, OQ of the tank 8.4. Formally evaluate aseptic process and terminal serialization 9. Product safety 9.1. Acceptable daily exposure determination and OEL 9.2. API industrial Hygiene analytical method development and validation 10. SymBio or CMO to provide transfer protocol including gap analysis and risk assessment on gaps and mitigation plan for reducing the risks (estimated duration 3-4 weeks) 11. SymBio or CMO should perform initial assessments on their CMO capabilities with BCV IV solution 11.1. Pump and nozzles evaluation on 2 mL vials 11.2. Suitability evaluation of manufacturing process with filling and packaging 11.3. Run a full/small scale IV batch to assess manufacturing capabilities to identify the critical process parameters 12. SymBio must perform the extractable/ leachable study from the container closure systems 13. CMO must perform the media fill or process simulation test 14. SymBio to provide MBR and PBR to Chimerix for review (estimated duration 4-6 weeks) 15. Chimerix to review MBR and PBR and comments (estimated duration 4 weeks) 16. Chimerix to provide MBR and PBR and all subsequent revisions (estimated duration 4 weeks) 17. CMO to manufacture a Demo/Engineering batch (estimated duration 4 weeks) 17.1. Test the specification T=0 17.2. Initiate stability study 17.3. Chimerix to be onsite 17.4. Tech transfer report 18. CMO to manufacture a cGMP/Clinical batch (estimated duration 4 weeks, 12 weeks after the Demo batch stability study initiation) 18.1. cGMP batch records including manufacturing and packaging 18.2. Initiate stability, including stability protocols 18.3. Chimerix to be onsite (optional) 19. CMO to produce DoE batches to evaluate the critical process parameters and their impact on critical product quality attribute (CPQA). Ideal to manufacture small scale batches if the capability permissible by CMO (estimated duration 8-10 weeks) 20. CMO to manufacture a DOE parameters confirmation /pre-validation batch (estimated duration 4 weeks) 20.1. Initiate stability, including stability protocols 20.2. Chimerix to be onsite (optional) 21. CMO to produce risk assessment documents on manufacturing process (estimated duration 4 weeks) 22. CMO to generate validation protocols 22.1. Facility 22.2. Equipment 22.3. Training of operators 22.4. Media fills 22.5. Aseptic operation 22.6. Microbiological 22.7. Manufacturing process 22.8. Packaging process 22.9. WFI 22.10. Environmental 23. CMO to manufacture [*] validation batches minimum 23.1. Master batch record 23.2. Stability, including stability protocols 23.3. Executed batch report 23.4. Validation report 23.5. All other reports including any deviations

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BCV Drug Substance for IV Liquid Product Transfer Activities

Month 1	1. Chimerix to provide drug substance manufacturing and analytical documentation including master batch records, analytical method validation reports, and specifications 1.1. Starting material/Intermediate method validation reports and specifications 1.1.1. [*] 1.1.2. [*] 1.1.3. [*] 1.1.4. [*] 1.1.5. [*] 1.1.6. [*] 1.2. Master batch records 1.2.1. [*] 1.2.2. [*] 1.2.3. [*] 1.2.4. [*] 1.3. Raw material (solvents and reagents) specifications 1.4. CMX001 method validation reports and release specifications 1.5. [*] and [*] validation protocols and reports 2. Chimerix to provide 2 kg of drug substance manufactured at [*] with retest extension based of stability 3. Chimerix to provide, if available, [*] of reference materials/markers for those used in CMX001 DS manufacturing. Intermediate markers that are maintained at [*] will remain at [*]

[*]

Months 3-5	4. Chimerix to provide [*] drug substance from final [*] validation batch (manufactured with WFi water) pending [*]
To be discussed	5. Chimerix to provide support for manufacture of [*] engineering batch (using WFi water) at [*] 6. Chimerix to provide support for manufacture of [*] validation batches (using WFi water) at [*]

Potential back up CDMO for BCV Drug Substance

Within 24 months from the Effective Date	7. 3-Phase Approach for Analytical Method Transfer 7.1. Phase 1 – SymBio to thoroughly examine product specification and methods, obtain all equipment and supplies needed for application of methods, and interface with Chimerix on any questions related to In-process test method and specifications 7.2. Phase 2 – SymBio and/or SymBio-chosen contract facility to perform analytical methods on R&D samples of finished product and informally compare data to data generated by Chimerix. SymBio and Chimerix to assess mock transfer data and determine if more work is needed or if formal transfer should proceed 7.3. Phase 3 – SymBio and/or SymBio-chosen contract facility to draft formal method transfer protocol and acceptance criteria. SymBio/SymBio-chosen contract facility approve formal method transfer protocol. SymBio/SymBio-chosen contract facility will receive and test representative samples and complete methods transfer activities and report

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

Within 24 months from the Effective Date	8. SymBio to provide the name of their selected CDMOs and Chimerix should assess their technical capabilities and review their facility for appropriateness 8.1. Facility capable of handling high potency API and dichloroethane (DCE) 8.2. Facility equipment/analytical instrumentation evaluation 8.3. Quality management system 9. SymBio should name their CDMO 10. RSM procurement ([*]) 10.1. CMX004 transfer 11. SymBio or CDMO to provide transfer protocol including gap analysis and risk assessment on gaps and mitigation plan for reducing the risks (estimated duration 3-4 weeks). Chimerix to review and provide documentation/support for technical transfer necessary to prepare for process validation 11.1. [*] transfer 11.2. [*] transfer 11.3. [*] transfer 11.4. [*] Milling 12. SymBio or CDMO should perform initial assessments on their CDMO capabilities with BCV API process including [*] and [*] 12.1. Run a full/small scale batch to assess manufacturing capabilities (time depends on scale) 13. SymBio to provide Master Batch Records to Chimerix for review (estimated duration 4-6 weeks depending upon CDMO) SymBio to provide translation of batch records and all other documents to be reviewed by Chimerix if they are not in English 14. Chimerix to review MBRs and comments (estimated duration 4 weeks)

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

EXHIBIT D

SYMBIO DEVELOPMENT PLAN

[*]

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

EXHIBIT E

FORM OF JOINT PRESS RELEASE

Chimerix and SymBio Pharmaceuticals Establish Strategic Collaboration for Antiviral Drug Candidate BRINCIDOFOVIR

– SymBio to develop BRINCIDOFOVIR for multiple antiviral indications –

[Intentionally left blank – text of joint press release to be determined.]

Exhibit 31.1

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

I, Michael A. Sherman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended September 30, 2019 of Chimerix, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2019

/s/ Michael A. Sherman

Michael A. Sherman

President & Chief Executive Officer

Exhibit 31.2

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

I, Michael T. Andriole, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended September 30, 2019 of Chimerix, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2019

/s/ Michael T. Andriole

Michael T. Andriole

Chief Business and Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Chimerix, Inc. (the "Company") for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Sherman, as Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 5, 2019

/s/ Michael A. Sherman
Michael A. Sherman
President & Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Chimerix, Inc. (the "Company") for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael T. Andriole, as Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 5, 2019

/s/ Michael T. Andriole
Michael T. Andriole
Chief Business and Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.